# EXHIBIT 16

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL | : | MDL NO. 1456 |
| INDUSTRY AVERAGE WHOLESALE | : | CIVIL ACTION: |
| PRICE LITIGATION | : | 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO | : | |
| U.S. ex rel. Ven-a-Care of | : | Judge Patti B. Saris |
| the Florida Keys, Inc. v. | : | |
| Abbott Laboratories, Inc., | : | Chief Magistrate |
| No. 06-CV-11337-PBS | : | Judge Marianne B. |
| - - - - - - - - - - - - - - -x | | Bowler |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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| STATE OF ALABAMA, | : | |
| Plaintiff, | : | |
| vs. | : | Case No.: CV-05-219 |
| ABBOTT LABORATORIES, INC., | : | Judge Charles Price |
| et al., | : | |
| Defendants. | : | |

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Page 174

MR. GOBENA: Object to the form.
A. Since I clearly wasn't doing it myself, yes.
Q. What did you expect of the individuals within your office when it came to factoring in information that came into the Office of Payment Policy regarding the cost to providers of drugs?
A. Of drugs? Was that the last word?
Q. Of drugs, yes, sir, drugs.
A. I'm not sure I had one. No one actually had, you know, their sole responsibility to deal with drug issues.
Q. But there were individuals in the office for whom it was one of their responsibilities, correct?
A. Right.
Q. And that would be Mr. Patashnik and the people who reported to Mr. Patashnik?
A. Yes, as one of their minor sidelines.
Q. You say minor sidelines. The drug payments for Medicare even during this time period, do you recall about what they were?

Page 175

A. Well, depending upon what time frame you're talking about, a couple of billion dollars excluding Epogen.
Q. And a couple billion dollars was a minor sideline?
A. In terms of what we might be able to do about it and in terms of spending time on issues such as durable medical equipment or physician issues, yes.
Q. When you say in terms of what you could do about it, what do you mean?
A. Well, we talked about having to change the regulations after '91 if we were going to do something about drug payment. That's what I'm talking about. There were other issues and other areas of the program that we could do something about administratively that did not require the amount of work that would have been required for changes in drug payments.
Q. So even if individuals within the office were aware of drugs available in discounts in excess of 20 percent from AWP, is it your testimony that

Page 176

your office devoted its resources to other things that promised greater savings?
MR. GOBENA: Object to the form.
A. Well, saving money was not the sole issue that caused our existence. It might be the IG's sole purpose, but we were always interested in paying the correct amount to the correct provider, physician, supplier, hospital, and being sure that the beneficiary paid no more in co-insurance that was -- than was absolutely necessary.
Q. Which raises the question I was getting to a little bit earlier, and that is whatever the range, given that -- strike that. If a drug were available at a range of prices and if HCFA were looking to pick one reimbursement price, were there factors that you considered in making that policy decision?
MR. GOBENA: Object to the form.
A. I don't remember.
Q. I mean, is it fair to say that in deciding what HCFA chose to pay for drugs reimbursable by Part B, that you would consider access to care for

Page 177

beneficiaries?
A. I would hope.
Q. And that if you picked a price point too low, it would impact access to care for beneficiaries, correct?
MR. BREEN: Objection to form.
MR. GOBENA: Also I'm going to instruct the witness the extent to which he needs to get into issues that are part of the deliberative process, I instruct you not to answer it, but if you can answer it otherwise, then please go ahead and answer.
THE WITNESS: Well, I think that one of the objectives for at least my office at the time was not to adversely impact the quality or quantity of patient care.
MR. COOK: Just so I know what he's not telling me, I don't quite understand when you tell him things that impact the deliberative process, what are you telling him not to tell me?
MR. GOBENA: Well, to the extent -- your questions are vague, so I'm not quite sure if you're asking about what gave rise to the '91 regulation,

Page 190

We discussed usual and customary and prevailing this morning.
Q. Uh-huh.
A. One would have to develop proxies for that at the beginning and then determine what the data was.
MR. GOBENA: Chris, I want to clarify, are you asking about the discussions with the Amgen representatives, the representatives from HHS and OIG, or are you starting to ask about the discussions between senior staff?
MR. COOK: I'm asking what Mr. Booth personally considered.
THE WITNESS: Well, this is what we discussed with Amgen.
BY MR. COOK:
Q. Okay. I'd like to know what you personally considered, not simply the conversations with Amgen, but you were the director of the Office of Payment Policy, you ultimately made a recommendation to the acting administrator of HCFA that HCFA adopt a fee schedule, correct?

Page 191

A. Yes.
Q. You indicated to me that in discussions with Amgen, the possibilities of an AWP methodology or reasonable charge methodology were discussed.
A. Yes.
Q. I think I've asked you whether you can remember any other methodologies that you personally considered, and that these three are the only ones that you recall right now, correct?
A. That's what I've said.
Q. What I'd like to know is not restricting this simply to conversations with Amgen, could you describe for me what you considered in connection with reasonable charge?
MR. GOBENA: I'm going to object and I'll have to instruct the witness not to answer to the extent that we're going -- that he's going to get into areas of deliberative process. The question as phrased, I don't know whether or not it would touch on discussions, deliberations that Mr. Booth had with any members of his staff, so --
MR. COOK: Feel free to instruct him not

Page 192

to answer.
MR. GOBENA: Okay.
BY MR. COOK:
Q. Mr. Booth, what factors did you consider in rejecting the reasonable charge in favor of the fee schedule for your recommendation to the administrator of HCFA?
MR. GOBENA: Same objection, instruct the witness not to answer on the basis of deliberative process.
BY MR. COOK:
Q. You considered average wholesale price as another methodology, correct?
A. Yes.
Q. And you ultimately rejected that methodology in favor of recommending a fee schedule, correct?
A. Yes.
Q. What factors did you consider in choosing a fee schedule over an AWP-based methodology?
MR. GOBENA: I'm going to object and instruct the witness not to answer on deliberative

Page 193

process grounds.
BY MR. COOK:
Q. What was your understanding of what an AWP-based methodology would entail as opposed to the fee schedule that you ultimately recommended?
A. Epogen is a drug that Amgen brought to market solely for patients with end-stage renal disease.
Q. Okay.
A. In order to bring Epogen to the market, Amgen in my parlance cannibalized themselves by selling the rights to the use of the drug to another company, so Medicare was basically Amgen's only customer since Medicare paid at the time about 96 percent of end-stage renal disease costs. By using AWP, Amgen would have set its own price. That was not in my judgment the best way to set the policy. In addition, I wanted a policy that would have controlled utilization.
Q. And what do you mean by controlling utilization?
A. Well, I'll try to explain it. The problem

Page 202

Q. Let me rephrase that. Why did HCFA reimburse at an amount greater than what it understood to be the ingredient cost for a provider who administered an appropriate dose of Epogen?
MR. GOBENA: Object to the form.
A. I think you've mischaracterized my remarks.
Q. You've indicated to me that the reimbursement amount for Epogen in many instances would exceed ingredient cost to the provider, correct?
A. No.
Q. No? Their ingredient cost would be less?
A. I don't think I said many.
Q. All?
A. Not all. Actually, most.
Q. Most. For those providers where the reimbursement amount exceeded the ingredient cost, did HCFA have an understanding of what that excess amount would be used to pay for?
MR. GOBENA: Object to the form. He's not a 30(b)(6) witness. You can answer in your personal

Page 203

capacity.
A. There was clearly going to be some spoilage of the drug because particularly at the beginning, it was difficult to make, difficult to ship, difficult to store. There were clearly going to be administration costs to administer the drug even where there was a shunt, and in some cases there wasn't, and we wanted to set the reimbursement rate high enough that facilities would administer Epogen to those patients who were receiving blood transfusions. And obviously this is not an exact science. We have only the clinical trials to base the judgments on that we made, and we said at the time that if it turned out that we had made incorrect judgments, that we would make adjustments in the price.
Q. After 1989, as I understand it, ESRD facilities would be paid based upon a combination of a composite rate in the separately billed drugs. Do I have that correct?
A. Not just after 1989.
Q. Before 1989 also, correct?

Page 204

A. From sometime in 1984, as I recall.
Q. So between 1989 and some point after 2001, ESRD facilities received both a composite rate payment and a payment for separately billable drugs, correct?
MR. GOBENA: Object to the form.
A. At least through 19 -- June of 1997.
Q. Between 1989 and June of 1997, did HCFA change the composite rate that ESRD facilities were paid for treating Medicare beneficiaries?
A. I don't remember.
Q. Do you recall any discussions about whether the composite rate should be changed in light of profits the facilities were making on the drug component?
MR. GOBENA: Chris, can I clarify? What discussions? Discussions with agency officials within the agency or --
MR. COOK: With anybody at all.
MR. GOBENA: Okay, I'll instruct you to not answer the question on deliberative process grounds the extent to which your answer would cover

Page 205

discussions within the agency.
THE WITNESS: Then I can only tell you that there were end-stage renal facilities that came to see us and wanted an increase in the composite rate.
BY MR. COOK:
Q. Do you recall what response you gave to those facilities about whether you would give an increase to the composite rate?
A. I recall very few increases in the composite rate.
Q. Do you recall expressing to any of these facilities the notion that the composite rate was not being increased because of money being made on the drug component?
A. Never.
Q. Do you recall internal discussions in which the decision not to raise the composite rate was tied to money being made on the drug component?
MR. GOBENA: I'm going to object and instruct the witness not to answer on deliberative process grounds.

Page 258

November of 1991, correct?
MR. GOBENA: Object to the form.
A. I believe it was November 25th, 1991, but I'd have to look it up.
Q. And do you recall, what was the payment methodology that was codified in that particular regulation?
A. I believe it was undiscounted AWP.
Q. Was it still the case in November of 1991 -- strike that. Did you participate in any discussions about why the Department of Health and Human Services published a regulation in November of 1991 paying undiscounted AWP rather than a discount off of AWP?
A. I don't recall the conversations.
Q. Did you make the decision to go to undiscounted AWP rather than discounted AWP?
A. I don't know -- I don't remember how the decision was made.
Q. But do you know whether you personally made it?
A. I did not make it.

Page 259

Q. Did you concur in that decision?
A. There were discussions about what we should pay, and the agency and the department made a decision.
Q. With whom did you have discussions about what you should pay?
A. Well, again, in the clearance process of the final rule, with the same parties that participated in the proposed rule.
Q. And do you remember the names of any of the people that you discussed this particular issue with?
A. I don't recall discussing this particular issue.
Q. Did you make known your disagreement with a policy paying at undiscounted AWP?
MR. BREEN: I'll object to the form.
MR. GOBENA: I'll allow the question to the extent you're asking a yes or no question, but if you're going to get into the substance of what he discussed with people in terms of his --
BY MR. COOK:

Page 260

Q. Let me ask it openly. Mr. Booth, what did you recommend should be the payment methodology in the final rule?
MR. GOBENA: I'm going to object and instruct the witness not to answer to the extent it reflects deliberative process discussions. If there's some discussion -- if there's some way you can answer the question without getting into discussions you had within the agency about the final rule, you can answer the question. Otherwise I'll instruct you not to answer it.
A. There were conversations with people outside the agency that suggested that for at least many individual drug codes, that a discounted AWP of 15 percent would be too harsh.
Q. And did you relay those discussions to anybody within the agency?
A. Well, some of them were reflected in the formal comments.
MR. COOK: Give me two seconds.
THE VIDEOGRAPHER: We're going off the record. The time is 4:57.

Page 261

(Discussion off the record)
THE VIDEOGRAPHER: We're going back on the record. The time is 4:58.
MR. COOK: Thank you very much, Mr. Booth. I apologize that we're going to bring you back again, but as we discussed off the record, I think we're going to convene for today. Mr. Breen has indicated that he has some questions. I have some more questions and other people do as well, and so we'll work with your counsel and with you and others to get a mutually convenient day so that we interrupt your life as little as possible.
THE WITNESS: Well, I've outlined some of my major time blocks, so within those constraints, hopefully we can find a mutually agreeable date.
MR. COOK: We'll do our absolute best. Thank you, sir.
THE WITNESS: Thank you.
THE VIDEOGRAPHER: We're going off the record. The time is 4:59. This marks the end of Videotape Number 5 and the conclusion of this day's deposition of Charles Booth.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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|---|---|---|
| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC., et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 146

from the pharmaceutical market that list prices, are essentially entirely meaningless and that only the weakest and smallest scale buyers pay anything close to it.
Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay $10 per bag, and a large purchaser who bought a very large volume would pay less than a dollar?
MS. BROOKER: Objection. Form.
A. I would not have been surprised.
Q. Okay. So, to that extent that -- President Clinton referring to a 10-to-1 ratio is something that would be consistent with your understanding of that particular market. Correct?
MS. BROOKER: Objection. Form.
Q. I'm sorry. You have to verbalize.
A. Again, I would have thought that market was a subset of the supplies market rather than the drug market.

Page 147

Q. That was my question. But you would have distinguished between the drug market, where 10-to-1 would not -- you would not expect to see. Correct?
A. That's correct.
Q. And the supply market, where sodium saline solution would be found, where there could be a huge variation between a small purchaser purchasing at list price and a very large purchaser purchasing at 99 percent off of list price?
MS. BROOKER: Objection. Form.
A. I would have made such a distinction, and I would not have been surprised to see those sorts of differentials of the supply market.
Q. And in between the commodities supply market of sodium saline and the patent-protected market of a brand name drug, would you expect generic drugs to be somewhere between those two extremes?
MS. BROOKER: Objection. Form.
MR. BREEN: Objection. Form.

Page 148

A. That would be a question I never thought about before today. But today I would say that we always made the distinction between -- between drugs and -- and supplies. And, again, I would fall back on the Medicare green eyeshade distinction between what's sterile supplies and what's pharmacy.
MR. COOK: Let's take a break.
THE VIDEOGRAPHER: The time is 11:28 a.m. We're going off the record, concluding Tape No. 2 in the deposition of Dr. Bruce Vladeck in the matter of In re Pharmaceutical Average Wholesale Price Litigation.
(Recess taken.)
THE VIDEOGRAPHER: The time is 11:46 a.m. We're going back on the record, starting Tape No. 3 of the deposition of Dr. Bruce Vladeck in the matter of In re Pharmaceutical Average Wholesale Price Litigation.
Q. Doctor, based upon what we were talking about just before the break, would it be fair to say that while you were administrator of HCFA,

Page 149

you did not understand published average wholesale price to be the average of prices at which wholesalers were selling their drugs to their customers?
A. It would -- it would be fair to say that I did not believe it was, in fact, an empirical estimate, that rather it was a -- an amount reported by the manufacturer to -- of the compendium compilers or whatever, yes.
Q. And, again, akin to a sticker price?
A. That's correct.
Q. Where did you get that understanding?
A. I believe that was probably what my staff explained to me when I first encountered the concept sometime after I took office.
Q. Do you recall anybody within HCFA who was under the belief that average wholesale price was an average of prices at which wholesalers sold drugs to customers?
MS. BROOKER: Object to form. And I would just instruct the witness, just, you know, be mindful of not disclosing deliberations,

Page 150

internal deliberations.
THE WITNESS: Understood.
A. I -- I think the most accurate way for me to answer the question -- I hope his response would be to say we did not believe -- I did not believe that it was an actually empirically-derived number in any form, that it was not necessarily, although it was possible, by chance, a reflection of what was occurring in the marketplace.
Let me perhaps expand on that. Again, the analogy of the sticker price was one that had great influence in my thinking, and I would probably have expected, at that point, that there were always some poor suckers who were paying that price, just like there's always folks who end up paying list.
Q. Were you familiar with the distinction between average wholesale price as published in these compendia, and a list price or direct price that manufacturers would -- would have for their products?

Page 151

MR. BREEN: Objection. Form.
MS. BROOKER: Objection. Form.
A. I would have understood, at the time, if someone had made that sort of intellectual distinction. I would -- again, trying to characterize precisely what I thought ten or 12 years ago -- I would have been perhaps puzzled or surprised, but probably not shocked to learn that there was a significant discrepancy between a formal published price list and an average wholesale price that appeared in a compendium.
Again, I would have -- let me not put so many negatives in there, perhaps for clarity. I would have expected that most published price lists conformed, by -- that manufacturers themselves issued to their salespeople or to their customers would have contained list prices that were equivalent to the average wholesale prices they reported to the compendium.
Q. Did you understand, between 1993 and 1997, then that AWP did not refer to the price at which a pharmaceutical firm sold a drug to its

Page 152

customer?
MS. BROOKER: Objection. Form.
MR. BREEN: Objection. Form.
A. Again, I would have expected there were some customers who, in fact, paid the average wholesale price, but I didn't not believe that it was an accurate reflection of the average revenue received by the manufacturer for -- or the wholesaler for a particular product.
Q. I guess to put it another way, you understood, between 1993 and 1997, that AWP did not represent the average acquisition cost for a pharmaceutical?
A. That's correct. We --
MS. BROOKER: Objection. Form.
MR. BREEN: Form.
A. -- we distinguished acquisition cost from average wholesale price, and believed that, in general, it was likely to be lower.
Q. I would like to get back a bit to the -- we were talking a bit about the relationship between published average wholesale prices and

Page 153

prices within the marketplace.
You indicated your belief about the relationship between AWP and prices in the marketplace for brand name drugs, I think.
Correct?
MS. BROOKER: Objection. Form.
A. I believe I did, yes.
Q. Okay. And -- and you testified, as I recall, that you thought that there was a percentage difference, on average, between published AWP's and prices within the marketplace.
Do I have that correct?
MS. BROOKER: Objection. Form.
A. That is correct.
Q. Regardless of whether that's what you testified before, I've correctly summarized what your belief was. Correct?
A. That's correct.
Q. When you say that it was an average, do I understand correctly it was your belief that it wasn't a fixed percentage between the two?

Page 174

A. That's correct.
Q. We were talking a little bit earlier about the -- the range of prices that a -- a commodity, a supply such as sodium chloride solution might have, being as much as 100-to-1. Correct? You recall that?
A. Yes.
Q. Okay. As to generic drugs, would it be consistent with your understanding, between 1993 and 1997, that a generic drug such as vancomycin could have a market range of prices as wide as that reflected in this chart?
MS. BROOKER: Objection. Form.
A. I am -- I think the most accurate way to answer that was I am surprised, as of today, to see that kind of data, and I think I would have been even more surprised, during the '93 to '97 period, to see that kind of data.
Q. But this is data that was reported to your agency. Correct?
A. That's -- that's my understanding, yes.
Q. And you would have expected members of

Page 175

your staff to have taken this data into account in either a -- and let's start with establishing Medicaid or Medicare reimbursement policy.
MS. BROOKER: Objection. Form.
A. I would have expected, given the nature of this report then, to have been much more influenced by the bolded section in the box on Page 2.
Q. And what aspect of that would you expect them to be influenced by?
A. Again, the finding that -- that most prices were, in fact, below the AWP, but that in two of the cases the differential was 15 to 20 percent.
Q. And that would refer, presumably, going back to Appendix 2, to the Calcigex and Inferon?
A. I -- presumably, yes.
Q. Because those were the single-source drugs. Correct?
A. Yes.
Q. And to the extent that Medicare reimbursed for the multiple-source drug here,

Page 176

vancomycin, would you expect your staff to take into account the difference between single-source drug prices and multiple-source drug prices in -- in considering changes to Medicare payment policies?
MS. BROOKER: Objection. Form.
A. The only thing I can observe empirically is that I don't recall, in our conversations over the years about changing Medicare drug pricing policy, the distinction between brand and generics arising very often, if at all.
Q. At the time this report was -- was written, am I correct that Medicare was reimbursing at undiscounted AWP for Part B drugs? Correct?
MS. BROOKER: Objection. Form.
A. I -- I believe that's correct.
Q. It was either EAC, according to survey --
A. Right.
Q. -- or AWP. Right?

Page 177

A. The only reason I hesitate in response to your question is trying to remember whether dialysis drugs were treated separately from other Part B drugs, but I don't believe they were.
Q. To the extent that -- that dialysis drugs were reimbursed pursuant to 405.517, they were being reimbursed by Medicare at 100 percent of AWP. Correct?
A. That is correct.
Q. And to the extent that the data on the chart at Appendix 2 is -- is accurate, that would indicate that for Calcigex, for example, if it were reimbursed under that methodology, am I correct that every single one of the providers surveyed would be reimbursed at an amount in excess of their acquisition cost? Correct?
A. That is correct.
Q. And for Inferon, all but two of the providers would have been reimbursed at above their acquisition cost. Correct?
MS. BROOKER: Objection. Form.
A. That's what it shows, yes.

Page 182

A. That's correct.
Q. One was EAC, established according to survey. Correct?
A. That's correct.
Q. We'll get to it later, but for whatever reason, that was not available to you because the surveys were not or could not be conducted?
A. That's correct.
MS. BROOKER: Objection to form.
Q. And so, your understanding was that pursuant to regulation, your only alternative between '93 and '97, while you were administrator of HCFA, was to pay based upon the published average wholesale price. Correct?
A. That's correct.
Q. And during the time that you were paying the published average wholesale price, you were aware that average wholesale price exceeded acquisition cost. Correct?
MS. BROOKER: Objection. Form.
A. Yes.
Q. You were aware that for generic drugs,

Page 183

the difference could be greater than for brand name drugs. Correct?
MR. BREEN: Objection.
A. I'm not certain I was aware of that.
Q. But for supplies such as sodium chloride, you were aware that the difference could be as much as 99 percent. Correct?
A. Yes, I was.
MR. BREEN: Objection. Form.
MS. BROOKER: Objection. Form.
Q. And the same would be true for other commodity products similar to sodium chloride such as, for example, dextrose in water.
Correct?
MR. BREEN: Objection. Form.
A. Yes, that's correct. Or sterile saline or something of that sort.
Q. Which are two of the other drugs at issue in this case. Correct?
A. I wasn't aware that -- that they were, but okay.
Q. And during that time, you, as

Page 184

administrator of HCFA, considered alternatives to 100 percent of AWP. Correct?
You, as administrator of HCFA, considered alternatives to reimbursing at 100 percent of AWP. Correct?
A. I don't know if we're getting into deliberative --
MS. BROOKER: You should be mindful that you should not disclose any pre-decisional deliberative process.
MR. COOK: I think it's going to be easier if you either direct him not to answer or let him answer, because I'm aware -- I'm a little leery of having the witness put in the difficult position of having to parse within his head --
A. Well, let me -- I can say I was aware that conceptually there were alternatives to 100 percent of AWP.
MS. BROOKER: Let me say you can state what your understanding was in your official capacity, and you can certainly state what the official policy was or the regulation, or what

Page 185

the statute was. You just cannot discuss pre-decisional deliberative conversations that you -- that you had with others.
THE WITNESS: I think I got that.
Q. All right. Without revealing what the deliberations were, were there deliberations within HCFA about alternative methods for reimbursing to undiscounted AWP?
MS. BROOKER: Objection to form.
A. Extensive discussion.
Q. Who -- who was involved in those extensive discussions?
A. I don't know if that gets too deliberative.
MS. BROOKER: You can say who was involved in deliberations.
A. I would say that with the exception of the Medicaid folks, the list of people I enumerated earlier as experts I would have consulted on these issues would have been involved, whoever the deputy administrator was at the time would have been involved. And, again,

Page 186

probably other members of the staff of the office administrator probably would have been involved, as would additional staff in the Office of Legislation and Policy, in addition to the individuals I named earlier.
Q. And it involved numerous meetings at which the -- the -- the possibilities were discussed; I take it?
MS. BROOKER: Objection. Form.
A. I would say we were, in 1996 and 1997 -- certainly probably beginning in 1995, there were very frequent conversations about budgetary issues and policies with potential budgetary impacts of one kind or another, and there was always a list of potential policies and changes to Part B drug reimbursement was frequently on those lists, and was not discussed at every meeting, but was frequently discussed.
Q. How many alternatives were discussed?
MS. BROOKER: Objection. You should not discuss exactly what -- you should not discuss any of your deliberations, so you

Page 187

shouldn't talk about -- I mean, that's -- that's prohibited.
MR. COOK: Well, are you instructing him not to answer?
MS. BROOKER: You can talk about what official policy was.
MR. COOK: All right. I'll make it easy.
Q. In your internal deliberations at HCFA, how many alternative methods of reimbursement did you consider?
A. I couldn't say. I -- it's not a question of privilege. I couldn't say.
Q. Okay. But within your internal deliberations, you did consider alternative methods of reimbursement. Correct?
A. That is correct.
Q. And, again, to -- to make the record as sharp as possible, what did you discuss in those deliberations?
MS. BROOKER: Objection. You cannot discuss exactly what your deliberations were.

Page 188

And I also object that these questions are incredibly vague. So, I object to form. I don't know exactly what program we're even talking about. I don't know what time period we're talking about. I don't know what the specifics are that you're talking about in this whole line of questions.
MR. COOK: But you understand enough that you won't let him answer it?
MS. BROOKER: If he's going to talk about internal deliberations. And -- and, again, just for the record, it's not that I won't let him talk about it. I am here to protect on -- not on behalf of the witness, but on behalf of the government, deliberative process privilege. It's not my privilege. It's not the witness' privilege. It's the federal government's privilege.
MR. COOK: All right. The United States, who has sued my client, will not allow the witness to talk about it.
Is that fair to say?

Page 189

MS. BROOKER: I don't think that's a fair characterization.
MR. COOK: Okay.
MS. BROOKER: Look, Chris --
MR. COOK: I know. I know.
MS. BROOKER: We have this issue before the Judge. There's no reason to bicker about it before the witness. Let's just all be professional about it.
Q. And so, it is fair to say that during the time you were the administrator of HCFA, the agency did not choose to change the manner in which it reimbursed Medicare Part B drugs?
MS. BROOKER: Objection. Form.
A. I would -- I would frankly personally object to that characterization because I had a growing feeling -- again, I would put this in a period probably beginning about 1995 through the time I left the government -- of frustration that we were significantly overpaying for Part B drugs, and that because of some combination, frankly, of political and legal constraints, we

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC., et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 370

you testified about, back on May 4th relating to going to an actual acquisition cost methodology for payment of drugs?

MS. BROOKER: Objection. Form.

A. That is my -- consistent with my memory of what we had proposed, yes.

Q. And could you describe what the payment methodology would have been if this statutory proposal had been adopted by Congress?

A. Well, again, it would have been lower of average wholesale price, now with -- with the little clause there under Section B, the opportunity to write regulations -- defining what average wholesale price was or actual acquisition cost, with a further provision that if there was insufficient information about the actual acquisition cost to the individual physician or supplier, we could employ national average data.

Q. Assuming that this is language from a budget proposal for the administration in Fiscal Year 1998, who would have actually drafted this language?

Page 371

A. Probably the actual -- the actual drafting of the language would have been done, I believe, by staff in the counsel's office at HHS, working with HCFA staff and staff of the Office of Legislation.

Q. Do you recall being involved in the crafting of -- of the language relating to this budget proposal?

A. I -- I don't believe I was involved in the actual language drafting, no.

Q. If you look at the -- Page 4 of the facsimile, which is Page 0322 on the Bates numbers, the second paragraph -- the first full paragraph at the top refers to a dispensing fee for pharmacies.

Absent this legislation, or at the time this legislation was proposed, Medicare did not pay a dispensing fee for pharmacies for drugs reimbursed under Part B. Is that correct?

A. That is correct.

Q. And this would have given the Secretary authority to pay entities such as Ven-A-Care an explicit dispensing fee.

Correct?

A. That's how I understand it, yes.

Q. Was there any discussion within HCFA that the creation of that dispensing fee was to make up, in some measure, for the lost profits from going from AWP to acquisition costs?

MS. BROOKER: Objection.

I would just instruct you to be mindful of not disclosing pre-decisional deliberations, and to just stick to policy.

A. I don't know if this addresses the objection of the concern or not. I don't recall any specific discussion about that. My presumption was that as a policy it would have the effect similar to what you described, but I don't have any specific memory of this provision at all, frankly.

Q. Okay. Who would be the best person to ask within HCFA for the -- the reason that this dispensing fee for pharmacies provision was included in the proposed legislation?

Page 373

A. I think probably again Ms. Buto or Mr. Hoyer.

Q. The other provision that piques my interest -- and unfortunately it's cut off -- is the Section 11237 immediately following. This says:

"Payments to physicians' assistants, nurse practitioners, and clinical nurse specialists."

And the first subheading refers to:

"Coverage in home and ambulatory settings in which a facility or a provider fee is not billed for physicians' assistants, nurse practitioners, and clinical nurse specialists."

First, do you know what that teaser of a heading relates to in terms of the proposed legislation?

MS. BROOKER: Objection. Form.

A. I have a surmise. I don't have any direct memory.

Q. And what would the surmise be?

A. My guess would be it would permit

should have known earlier; that, in fact, the 15 to 25 percent or 15 to 20 percent was the rule of thumb for sole-source brand drugs, that, in fact, the expectation, the belief about generics, was that it was more likely to be between 25 and 40 percent difference between actual market price and average wholesale price.

Q. So, when you testified about your belief that the difference was somewhere between 15 and 20 percent, you were just talking about your own personal belief and not the belief of others at HCFA. Is that correct?

MS. BROOKER: Objection to form.

A. I think it's fair to say that my own beliefs were formed on the basis of what I was told by my colleagues at HCFA. So, I think if I described that as the consensus view among the people I would have consulted or would have advised me about the issue, that would be a fair characterization, because there's nowhere else from which I would have got that impression.

Q. Did you have discussions with



others at HCFA prior to 1996 or 1997 concerning what the difference between AWP and transaction prices was for generics?

MS. BROOKER: Objection.

I would ask you also to be mindful of not discussing predecisional deliberative conversations.

A. I think I can say that, again, in thinking about the average wholesale price and its relationship to anything else, it was not prior to then that I distinguished between generics and brand name drugs and, therefore, it's unlikely I would have had such a conversation at all.

Q. Okay. How many people worked at HCFA during the time that you were there?

MS. BROOKER: Objection.

A. About 4,000.

Q. And did some of those people have the responsibility to understand what was going on in the marketplace?

MS. BROOKER: Objection.

A. That's an interesting question and



a somewhat sore subject. I don't know that there was anyone in the agency who had specific responsibility for detailed knowledge of the prescription drug marketplace.

Q. I take it some of them did have knowledge of the prescription drug marketplace. Is that correct?

MS. CONNOLLY: Objection to form.

A. That was my perception.

Q. Let's take a look once again at the 1991 regulation. I believe it's been marked as Exhibit Abbott 261?

A. Yes, sir.

Q. And I believe you may have testified earlier that you had seen this regulation before. Is that correct?

A. That is correct.

Q. What I want you to do is look at the page with the No. 62 in the upper right-hand corner.

A. Yes, sir.

Q. Under the "comment" section it --



it talks about the reimbursement level for drugs and it says:

"We received a great many comments on this issue, primarily from oncologists, indicating that our 85 percent standard was inappropriate."

Was it your understanding that originally HCFA proposed that the reimbursement level be set at 85 percent of AWP?

MS. BROOKER: Objection.

A. Yes.

Q. And it published a proposed reg and then solicited comments from interested persons. Is that correct?

A. The typical administrativesque process, yes.

Q. Okay. And the next sentence says:

"The thrust of most of the comments was that many drugs could be purchased for considerably less than 85 percent of AWP, particularly multisourced drugs, while others were not discounted."

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL | ) | MDL NO. 1456 |
| INDUSTRY AVERAGE WHOLESALE | ) | CIVIL ACTION |
| PRICE LITIGATION | ) | 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO | ) | |
| U.S. ex rel. Ven-a-Care of | ) | Judge Patti B. Saris |
| the Florida Keys, Inc. | ) | |
| v. | ) | Chief Magistrate |
| Abbott Laboratories, Inc., | ) | Judge Marianne B. |
| No. 06-CV-11337-PBS | ) | Bowler |

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(captions continue on following pages)

Videotaped deposition of THOMAS A. GUSTAFSON

Volume I

Washington, D.C.

Friday, September 28, 2007

9:00 a.m.

Page 174

A. I do not know.
Q. Who would know?
A. If I had world enough and time I would ask Bob Neimann if he had ever done such a thing, understanding that the payment environment of some of these other programs was not comparable to that of the Medicaid -- excuse me -- Medicaid or Medicare programs.
In particular those are vendor payment programs, which means that the program pays -- sometimes the term is reimburses -- a provider for services that they provide. In a number of other government programs the provider is in fact a part of the program. Veterans Administration is the most evident. Indian Health Service same characteristic. Defense Department same characteristic.
So their processes for paying for and delivering drugs is likely to be very different. So whether that would be a fruitful endeavor, a fruitful area for staff to spend time on, would be an open question. I mean, a question one could

Page 175

raise ex ante before you even ask the question.
Q. You drew a distinction in your response between Medicare and Medicaid paying for or reimbursing for drugs.?
MR. WINGET-HERNANDEZ: Objection, form.
Q. In your last answer, Mr. Gustafson -- am I pronouncing it right, Gustafson?
A. Gustafson is fine.
Q. In your last answer did you draw a distinction between a vendor drug program --
A. Vendor payment program was the term.
Q. A vendor payment program.
A. Was the term I used.
Q. Let me start over. I mucked it all up.
In your last answer, Mr. Gustafson, did you draw a distinction between a vendor payment program paying for or reimbursing for a drug?
A. Mm-hmm.
Q. Yes?
A. I drew that distinction, correct.
Q. What is the significance of that distinction?

Page 176

A. The principal payment policy, the Medicare program in general pays providers for services in almost all instances now at prices that are established in advance by the agency. This is thought of as different from a world of reimbursement, although that term is commonly used to cover what I've just described. But those of us who are immersed in the technical details of payment policy understand reimbursement to be a notion which would be more applicable in the old world of cost-based payments so that you are filling someone's purse after they have emptied it.
The notion there is that the provider decides how much they should be paid as opposed to the program. So this distinction has mattered to the agency at different times. And in fact portions of the agency have been renamed in order to remove the remove the word reimbursement.
Q. The current system in place for paying for part B drugs under Medicare part B is that a payment system or a reimbursement system?
A. That's payment system.

Page 177

Q. Between 1991 and 2001, beginning with the promulgation of regulations in November 1991 through 2001 under Medicare part B for physician administered drugs, was that a payment system or a reimbursement system?
A. As I understand it, you'd have to characterize it as payment system if you want to draw that distinction. In other words, the agency set, established, endorsed, acquiesced and used a set of payment rates that were known in advance, that were not differentiated by a particular provider, but which established a payment rate that carriers and FIs used in order to pay.
Does that answer your question?
Q. Yes, it does.
Do you know what factors CMS took into account in determining what rate it should pay for part B covered drugs?
MR. MAO: Tom, you should respond to the question again with the caveat to the extent that if your response requires you to reveal deliberations --

Page 186

exactly how we did it, we deflected the attention of the carriers from that program memorandum.
Q. This is another interrogatory response that you verified.
A. So it must be true then, right?
Q. It must be. If you could look to the last paragraph of the response --
A. Which page are we on?
Q. On page 54.
A. Persons who had a role? Is that when you're looking at?
Q. Correct. The previous paragraph states that the government will produce copies of two program memoranda dated September and November of 2000. And then the next paragraph gives a list of individuals' names. Do I have that correct?
A. Yes.
MR. MAO: Object to the form.
Q. Is that the interrogatory response that you were verifying the accuracy of?
A. That is correct.
Q. And was it accurate, by the way?

Page 187

A. As far as I know, yes.
Q. If you could turn back --
A. To the best of my knowledge and belief.
Q. If you could turn back to interrogatory number 15 on pages 52 and 53 and just look through the various subdivisions of information that was requested in interrogatory number 15. Mr. Gustafson, could you have responded to all of the provisions of interrogatory number 15 if you had been asked to do so?
MR. MAO: Objection, form.
A. Are you asking me if I had substantive knowledge that would have enabled a fuller discussion than is in this document?
Q. In part, yes.
A. And is there some other part?
Q. Well, to start, do you understand what interrogatory number 15 is requesting?
A. Let me read it. (Reading).
I have read it. Will you reengage the question here?
Q. Do you understand interrogatory number

Page 188

15?
A. I'm sorry.
Q. Do you understand what interrogatory number 15 is asking?
A. Yes.
Q. I'm not asking you to do so, but given time could you give a complete response to interrogatory number 15?
MR. WINGET-HERNANDEZ: Objection, form.
MR. COOK: You're right. I ought to drop the adjective.
BY MR. COOK:
Q. Could you provide a fuller response to interrogatory number 15 than is provided here in the written response?
MR. MAO: Objection, form.
A. That calls upon me to make an interpretation of what fuller might mean. The response to the -- the response that I verified here makes reference to these two documents, AB 0086 and AB 0085, which I have not reviewed lately. So I'm not sure if I can go beyond what is said in

Page 189

those documents. B is covered by this last paragraph I believe quite effectively.
So I'm not sure if I can give you a better answer than that.
Q. Sitting here today, correct?
A. Correct.
Q. In December of 2006 could you have personally or through the offices of people with whom you worked explained why HCFA issued program memorandum AB-00-86 to Medicare carriers?
MR. MAO: Objection, form. And also, again, you can go ahead and answer except to the extent that your response would require you to discuss internal deliberations that ultimately resulted in the guidance or directive that was published by the agency.
A. If you are asking me could I have written more words on the page, then yes.
Q. The second question of course would be would those words have been accurate?
MR. WINGET-HERNANDEZ: Object to the form.

Page 190

A. Well, of course. I would have verified them. Therefore they would have been accurate. No. I'm sorry. I don't mean to be flip.
Bumping in again to the question of I'm not recalling exactly what was in those two documents I referred to a moment ago, I'm not sure if it would have expanded one's understanding too much beyond what was there. And I believe, having discussed this previously with counsel, that I can't go beyond what I've said already without bumping into questions of deliberative privilege.
Q. And without going into what the response would have been, are there any aspects of interrogatory number 15 that you either do not understand or that you believe the agency would be incapable of providing a full response to?
MR. MAO: Objection, form.
A. Repeat the question, please.
Q. Sure. I'll break it down into two. I think you've already testified that you understand what the interrogatory is requesting, right?
A. I've got it.

Page 191

Q. Would the agency, CMS, in your experience be capable of answering the questions posed in interrogatory number 15?
MR. MAO: Objection, form.
A. You're going to have to be more precise, I think, because I keep bumping into we answered this. Here is AB 0086 and AB 00115. So are you alleging to me that those documents do not answer these questions?
Q. It certainly is not your contention, is it, that providing the documents provides an answer to the first question, which is to explain why the agency --
A. Well, I don't know what it says in that document. Frequently we do say why we are doing things. Is that everything that might be said on that subject? Perhaps not. But bingo, deliberative privilege.
Q. Leaving aside questions of deliberative process privilege and whether it applies, whether it's been waived, all issues beyond the scope of this conversation, could the agency have explained

Page 192

why HCFA issued AB-00-860 Medicare carriers?
MR. MAO: Objection, form.
A. The agency explains things in policy documents of which this is one. So insofar as the agency has something to say it says it in cleared documents in relevant form and so forth and so on. So I don't think it's answerable to know what the agency could have said in some other document that it didn't say here.
If on the other hand the question is were there folks within the agency who were involved in these decisions who might be able to provide additional detail about what was motivating the agency to proceed as it did, insofar as that is not sufficiently clear in the published documents already, conceivably that could be true.
Q. And you of course verified the response to this particular interrogatory, correct?
MR. WINGET-HERNANDEZ: Objection, form.
A. I signed it, yes.
MR. WINGET-HERNANDEZ: You need to give us a chance to interpose our objection so we don't

Page 193

have this problem. If you'll just wait for a second so we can speak and then answer.
THE WITNESS: I'm sorry.
Q. Do you have any reason to believe that the agency could not have provided additional information in response to interrogatory number 15, leaving aside questions of privilege?
MR. MAO: Objection, form.
A. Do I have any reason to believe -- please repeat the question.
Q. Sure. I'll reread it. Do you have any reason to believe that the agency could not have provided additional information in response to interrogatory number 15, leaving aside questions of privilege?
A. I have no reason to believe they could not have insofar as the whatever is in this document did not fully cover the matter. And I don't know the answer to that question. And obviously deliberative privilege -- deliberative process privilege -- excuse me -- enters this profoundly.

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL : MDL NO. 1456

INDUSTRY AVERAGE WHOLESALE : CIVIL ACTION

PRICE LITIGATION : 01-CV-12257-PBS

THIS DOCUMENT RELATES TO :

U.S. ex rel. Ven-a-Care of : Judge Patti B. Saris

the Florida Keys, Inc. :

v. :

Abbott Laboratories, Inc., : Chief Magistrate

No. 06-CV-11337-PBS : Judge Marianne B.

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(CROSS NOTICED CAPTIONS ON FOLLOWING PAGES)

Videotaped deposition of DR. THOMAS A. GUSTAFSON

Volume II

Washington, D.C.

Monday, December 17, 2007

9:19 a.m.

Page 257

billion claims a year, and the administrative resources available are slender, and not typically increased when Congress puts on new mandates for different changes in law.

So in this instance, we more or less stayed still, as I recall, and continued to use the Red Book-based average wholesale price as a reasonable way of proceeding in reflecting the statute.

BY MR. COOK:

Q. Now, as I understand this particular statute, the Balanced Budget Act of 1997, was addressed to the agency, correct?

A. The mandate typically runs to the Secretary, but allowing that precision, yes.

Q. So the mandate runs to the Secretary who then delegates it to the agency, in this case it was HCFA, right?

A. That's correct.

Q. You said that the agency first must interpret the statute to determine what the mandate is, right? I'm sorry. You have to verbalize. Is

Page 258

that correct?

A. I believe so. Yes.

Q. How did the agency interpret the statute in this particular instance?

A. I think it's well-known. We used average wholesale price in the Red Book as a reflection of average wholesale price as called for by the statute.

Q. Who made the decision to interpret the statute in that manner?

MR. MAO: You can answer except to the extent that it reveals deliberative process and deliberative discussions that they had internally.

MR. AZORSKY: Objection to form.

THE WITNESS: I don't think I can say anything on that subject without invading deliberative process questions.

BY MR. COOK:

Q. Well, let me break it down just a little bit. Congress gives a mandate to pay 95 percent of the average wholesale price, correct?

A. Uh-huh.

Q. Someone within the agency has to make a

Page 259

determination that in order to put that mandate forward, the agency is going to engage in this particular course of conduct, correct?

A. Uh-huh.

Q. And in this instance, the agency had available to it at least two courses of conduct. One, as I see it, and you can correct me if I'm wrong, was to continue doing what it was doing, which was to look it up in the compendium, correct?

A. Uh-huh.

Q. I'm sorry. You have to verbalize.

A. Excuse me. When you say verbalize, you want me to talk.

MR. AZORSKY: Objection. Form.

BY MR. COOK:

Q. Were there other courses of action available to the agency to implement that mandate?

A. Yes, conceivably. I mean, there certainly were other compendia available other on the Red Book. And if I understood the landscape at the time correctly, the Medicare carriers had traditionally and typically, if not by our instruction, used the

Page 260

Red Book, where as I understand the Medicaid program more typically used the Blue Book.

Having said that, I couldn't tell you what the differences of those two, and I don't think I ever saw either of them. It's not like there was a Blue Book on my credenza and a Red Book standing next to it. So there were alternative sources of information available in a published form similar to the, to the Red Book. It would be conceivable for us to have mounted a survey operation of our own in order to attempt to acquire this information in a more direct fashion, have exactly what was going on more under our own control.

As I can speak as a general matter, the agency is called upon in all manner of forms to implement statutory directives. They typically do this in a regulatory context. Sometimes initial implementation goes out through program instructions, but eventually we rely on regulations -- excuse me, the agency relies on regulations, to be precise about my pronouns here, since I'm no longer affiliated with the agency.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC.,<br>et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

an exit and entrance conference are?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: When we begin a study, we typically have a meeting with staff at CMS that are interested in the topic, provide them a design of the work that we're planning to do, sort of a research design, and get their feedback on what we're planning to do, see if they think that it's a good topic and if there might be better ways for us to approach the subject.
When we finish a report, before it goes out in an official draft, we have an exit conference with CMS, where we share with them a working-draft version of the report and get their feedback on it.
BY MR. TORBORG:
Q. Are -- are records kept of these meetings?
A. Yes.
Q. How are they kept?
A. Someone on the team will typically type



up the notes, the meeting notes.
Q. Have you ever typed up the meeting notes?
A. Yes.
Q. Okay. And where are those kept?
A. In a primary file in the -- in the report file.
Q. Can you think of any better place to learn what happened at these meetings, entrance and exit conference meetings, than those notes?
MR. NEAL: Objection as to form.
THE WITNESS: No.
BY MR. TORBORG:
Q. How many people typically attended the exit conference meetings?
A. It really depends. It might be as low as, you know, six or seven people, up to 25 or 30.
Q. Have any of the exit conferences that you've been involved in included 25 or 30 people?
A. Yes.
Q. Do you recall with respect to what reports?



A. I know the federal upper limit reports usually get a decent-sized crowd. I don't recall any particular Medicare reports. I mean, typically, you know, they might draw 15 or 16 people.
Q. Do you know why the federal upper limit ones usually draw a larger crowd?
A. No.
Q. Who else from OIG attends the exit conferences?
A. Typically one or both managers in the office, so Rob Vito and Linda Ragone or Rob Vito and myself, along with the staff that worked on the project, the other analysts in the regional office that worked on the project, as well as a program specialist in Baltimore.
Q. Do you recall the names of the program specialists who were involved in exit conferences relating to reimbursement of drugs?
A. Linda Abbott, Sara Craren, Linda Frisch, Lisa Foley, Bambi Straw.
Q. In your discussions with CMS, have they



ever expressed frustration to you about drug reimbursement?
MR. NEAL: I'm going to instruct the witness not to answer that question and put an objection on the record.
MR. TORBORG: What's the basis of the objection?
MR. NEAL: He's mentioned that his conversations with CMS personnel have taken place at exit and entrance conferences. We believe those conferences are integral to the deliberative process privilege. They are predecisional discussions with agency personnel relating to policy development, and as a result, we've asserted a privilege over the subject of those conversations. Your last question, I believe, would necessarily implicate those conversations.
BY MR. TORBORG:
Q. Without telling me the specific words that were said at these conferences, can you tell me your understanding of whether or not they were frustrated?

Page 90

MR. NEAL: I'm going to instruct the witness not to answer, so... That would reveal the substance of the communication, so my objection stands.
BY MR. TORBORG:
Q. Mr. Tawes, you understand that you're here today in connection with a lawsuit that The United States has brought against Abbott, correct?
A. Yes.
Q. Do you have an understanding of the nature of that lawsuit?
A. No.
Q. When did you first become aware that there was an under-seal case brought against Abbott and other manufacturers of drugs?
A. When the first person in our office got deposed.
Q. And do you know who that was?
A. I believe it was Nancy Molyneaux.
Q. Did you talk to Nancy Molyneaux about her deposition?
A. No.

Page 91

Q. Have you talked to any of the -- of your office mates about the testimony they've given in this case?
A. Aside from the general question, how'd it go, and receiving nothing except a nod or something like that, no.
Q. What -- what do you mean by a nod?
A. Meaning (indicating), it was fine or okay. I mean, none -- there was -- none of the contents of the depositions were discussed.
Q. So in your discussions with your office mates, the only thing you've talked about with respect to deposition and the only correspondence you've had has been a nod, right?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: Similar to that. It was -- I wouldn't call it a discussion. It would be a question such as, are you glad it's over, you know, and hearing (indicating) yes, you know. That's -- that -- it's not really a discussion.
BY MR. TORBORG:

Page 92

Q. Have you ever reviewed any internal Abbott documents?
A. Not that I know of.
Q. And I think I asked you this before, but do you have an understanding of -- a general understanding at all about what it is that the government alleges that Abbott did wrong in this case?
MR. NEAL: I'm going to object to the question and instruct the witness:
You can answer that to the extent that it doesn't reveal communications that you've had with your attorneys in this case.
THE WITNESS: I assume that it's similar to the other legislation [sic] that the -- that has been brought against other manufacturers. So I don't know the specifics of the case, no.
BY MR. TORBORG:
Q. And when you say "similar to other the legislation," do you mean lawsuits?
A. Yeah, that's what I -- yeah. That's what I meant. Sorry.

Page 93

Q. That's all right.
A. I misspoke.
Q. That's all right. And your understanding of those other litigations is what?
MR. NEAL: I'll object to the form.
You can answer.
THE WITNESS: It goes back to what I said about Tapp and AstraZeneca.
BY MR. TORBORG:
Q. Okay. Sorry. I'm just trying to find a new writing utensil.
What did you do to prepare for today's deposition?
A. I reviewed the -- the deposition notice, I provided -- I met with my attorneys; I provided computer files, e-mails, and primary and secondary files from our reports.
Q. When did you meet with your attorneys?
A. Two or three weeks ago. I don't remember the exact date. And I also saw them briefly yesterday.
Q. Okay. And how long did you meet with

Page 178

And then using my highlighter, would you highlight the ones that were -- that are multiple-source, MS?
A. (Complies.)
Q. Now, as you review that schedule, does anything pop out at you in the Percent Saved column for the highlighted columns, multiple-source drugs?
MR. NEAL: Objection as to form.
THE WITNESS: That there is large potential savings for almost all of the -- as far as percent saved, for the multiple-source drugs.
BY MR. TORBORG:
Q. And does that mean there was a larger difference between acquisition cost, as shown in the market and shown in the pricing catalogs, and the AWPs?
MR. NEAL: Objection as to form.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. Okay. Do you recall discussions at OIG relating to the fact that there were such large differences between the catalog prices for

Page 179

multiple-source drugs and the AWPs for those drugs?
A. I don't recall talking about multiple-source drugs specifically.
Q. How about generics?
A. Or -- or generics specifically. I mean, obviously we did some specific studies on a few of these projects because of the large spreads we found in here.
Q. But fair to say that your -- as reflected in this chart, which provides the detail of your report, right, shows very large savings potential for multiple-source drugs --
MR. NEAL: Objection to --
BY MR. TORBORG:
Q. -- right?
MR. NEAL: -- the form.
THE WITNESS: Again, large savings potential as a -- as a percentage, not necessarily as a total dollar figure.
BY MR. TORBORG:
Q. Do you think it's appropriate to evaluate the differences between prices as a

Page 180

percentage?
MR. NEAL: Objection as to form.
THE WITNESS: I think it's certainly one way to evaluate it.
BY MR. TORBORG:
Q. You -- do you recall any discussions at any time at OIG with the fact that there was such large spreads for generic multi-source drugs?
A. Not generic as a whole. Again, for a couple particular products, we certainly discussed it.
Q. And which products were those?
A. That would be Albuterol and Leucovorin Calcium, I remember specifically.
Q. What do you recall about Leucovorin Calcium?
A. That in later -- a couple later reports that I worked on, it was a generic, I believe, cancer drug that seemed to have AWPs that were vastly out of line with actual acquisition costs.
Q. Did you have any discussions with individuals at CMS about the large percentage

Page 181

differences in the -- in the prices for generic drugs between actual acquisition cost, as shown in catalogs, versus published AWPs?
MR. NEAL: I'm going to object to the question.
I'll instruct you not to answer to the extent that those -- your answer would reveal communications that took place in the context of entrance or exit conferences with CMS personnel.
THE WITNESS: Not outside of entrance or exit conferences.
BY MR. TORBORG:
Q. Do you recall having the discussions at all?
MR. NEAL: I'm going to instruct the witness not to answer that question.
MR. TORBORG: Can I ask him whether, without divulging specific communications, if he recall the discussions happening at all?
MR. NEAL: The problem is, the discussions you're talking about involve a specific substance area.

Page 182

MR. TORBORG: That I think is important to the case; that's why I'm asking about it.
MR. NEAL: That may be, but, you know, that -- that doesn't play into our privilege -- privilege assertion, so...
MR. TORBORG: So what you're saying, in essence, is regardless of how important it may be to my defense, you're still going to assert the privilege, no matter what?
MR. NEAL: You can characterize it however you want to. I mean, the fact is, this is an important governmental privilege, and we're going to assert the privilege in this case. We have motions pending on -- you know, on this matter as we speak, and the Court will presumably resolve it for us.
MR. TORBORG: Okay. Hopefully this will be of assistance.
BY MR. TORBORG:
Q. If we go to Page 10 of your report, Recommendations, what was the purpose for the Recommendations section of the report?

Page 183

A. To make recommendations to CMS about how they could impact or -- or implement some of the changes that would be called for by the findings of our report.
Q. Did you attend the exit conference for this report?
A. I don't believe so.
Q. Do you recall any discussions with CMS about this report?
A. No.
Q. If you look at page -- I'm sorry -- the section under Discounted Wholesale Price, that recommendation, the fifth sentence down, it starts with, In addition. Are you with me?
A. Uh-huh.
Q. It says: In addition, the secretary should be granted the authority to conduct sample surveys of actual wholesale prices to determine the amount of difference between actual average wholesale prices and published AWPs. The percentage difference found in the sample could then be applied to all AWPs used by the program to

Page 184

determine drug reimbursement.
Do you have an understanding of what that recommendation is -- is all about?
A. Yes.
Q. Do you recall discussing -- discussing that recommendation with anyone at CMS at any time?
MR. NEAL: Objection.
You can answer that to the extent that you don't reveal the substance of communications that took place at exit or entrance conferences.
THE WITNESS: No.
BY MR. TORBORG:
Q. The second recommendation is Acquisition Cost. It states: Medicare could base the payment of drugs on either actual or estimated acquisition costs. Although Medicare currently has the authority to use EAC, carriers have yet to successfully implement the option.
Do you recall any discussions about the inability to use the estimated acquisition cost approach in reimbursing Medicare Part B drugs?
A. No.

Page 185

Q. By the time you came in, in 1997, estimated acquisition cost was sort of a methodology of the past; is that fair to say?
MR. NEAL: I'll object to the form.
You can answer.
THE WITNESS: In Medicare, yes.
BY MR. TORBORG:
Q. How about for Medicaid?
A. In Medicaid, as far as I know, estimated acquisition cost is still on the books, and it's up to states to determine the definition -- or not the definition, but it's up to states to determine what estimated acquisition cost is.
Q. Okay. And do you recall any discussions at OIG about whether or not states were implementing that requirement in accordance with the law?
MR. NEAL: Objection as to form.
THE WITNESS: I don't think the law gave them specific instruction about how to implement the requirement.
BY MR. TORBORG:

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

| | | |
|---|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

| | | |
|---|---|---|
| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC.,<br>et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 86

an exit and entrance conference are?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: When we begin a study, we typically have a meeting with staff at CMS that are interested in the topic, provide them a design of the work that we're planning to do, sort of a research design, and get their feedback on what we're planning to do, see if they think that it's a good topic and if there might be better ways for us to approach the subject.
When we finish a report, before it goes out in an official draft, we have an exit conference with CMS, where we share with them a working-draft version of the report and get their feedback on it.
BY MR. TORBORG:
Q. Are -- are records kept of these meetings?
A. Yes.
Q. How are they kept?
A. Someone on the team will typically type

Page 87

up the notes, the meeting notes.
Q. Have you ever typed up the meeting notes?
A. Yes.
Q. Okay. And where are those kept?
A. In a primary file in the -- in the report file.
Q. Can you think of any better place to learn what happened at these meetings, entrance and exit conference meetings, than those notes?
MR. NEAL: Objection as to form.
THE WITNESS: No.
BY MR. TORBORG:
Q. How many people typically attended the exit conference meetings?
A. It really depends. It might be as low as, you know, six or seven people, up to 25 or 30.
Q. Have any of the exit conferences that you've been involved in included 25 or 30 people?
A. Yes.
Q. Do you recall with respect to what reports?

Page 88

A. I know the federal upper limit reports usually get a decent-sized crowd. I don't recall any particular Medicare reports. I mean, typically, you know, they might draw 15 or 16 people.
Q. Do you know why the federal upper limit ones usually draw a larger crowd?
A. No.
Q. Who else from OIG attends the exit conferences?
A. Typically one or both managers in the office, so Rob Vito and Linda Ragone or Rob Vito and myself, along with the staff that worked on the project, the other analysts in the regional office that worked on the project, as well as a program specialist in Baltimore.
Q. Do you recall the names of the program specialists who were involved in exit conferences relating to reimbursement of drugs?
A. Linda Abbott, Sara Craren, Linda Frisch, Lisa Foley, Bambi Straw.
Q. In your discussions with CMS, have they

Page 89

ever expressed frustration to you about drug reimbursement?
MR. NEAL: I'm going to instruct the witness not to answer that question and put an objection on the record.
MR. TORBORG: What's the basis of the objection?
MR. NEAL: He's mentioned that his conversations with CMS personnel have taken place at exit and entrance conferences. We believe those conferences are integral to the deliberative process privilege. They are predecisional discussions with agency personnel relating to policy development, and as a result, we've asserted a privilege over the subject of those conversations. Your last question, I believe, would necessarily implicate those conversations.
BY MR. TORBORG:
Q. Without telling me the specific words that were said at these conferences, can you tell me your understanding of whether or not they were frustrated?

Page 90

MR. NEAL: I'm going to instruct the witness not to answer, so... That would reveal the substance of the communication, so my objection stands.
BY MR. TORBORG:
Q. Mr. Tawes, you understand that you're here today in connection with a lawsuit that The United States has brought against Abbott, correct?
A. Yes.
Q. Do you have an understanding of the nature of that lawsuit?
A. No.
Q. When did you first become aware that there was an under-seal case brought against Abbott and other manufacturers of drugs?
A. When the first person in our office got deposed.
Q. And do you know who that was?
A. I believe it was Nancy Molyneaux.
Q. Did you talk to Nancy Molyneaux about her deposition?
A. No.

Page 91

Q. Have you talked to any of the -- of your office mates about the testimony they've given in this case?
A. Aside from the general question, how'd it go, and receiving nothing except a nod or something like that, no.
Q. What -- what do you mean by a nod?
A. Meaning (indicating), it was fine or okay. I mean, none -- there was -- none of the contents of the depositions were discussed.
Q. So in your discussions with your office mates, the only thing you've talked about with respect to deposition and the only correspondence you've had has been a nod, right?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: Similar to that. It was -- I wouldn't call it a discussion. It would be a question such as, are you glad it's over, you know, and hearing (indicating) yes, you know. That's -- that -- it's not really a discussion.
BY MR. TORBORG:

Page 92

Q. Have you ever reviewed any internal Abbott documents?
A. Not that I know of.
Q. And I think I asked you this before, but do you have an understanding of -- a general understanding at all about what it is that the government alleges that Abbott did wrong in this case?
MR. NEAL: I'm going to object to the question and instruct the witness:
You can answer that to the extent that it doesn't reveal communications that you've had with your attorneys in this case.
THE WITNESS: I assume that it's similar to the other legislation [sic] that the -- that has been brought against other manufacturers. So I don't know the specifics of the case, no.
BY MR. TORBORG:
Q. And when you say "similar to other the legislation," do you mean lawsuits?
A. Yeah, that's what I -- yeah. That's what I meant. Sorry.

Page 93

Q. That's all right.
A. I misspoke.
Q. That's all right. And your understanding of those other litigations is what?
MR. NEAL: I'll object to the form.
You can answer.
THE WITNESS: It goes back to what I said about Tapp and AstraZeneca.
BY MR. TORBORG:
Q. Okay. Sorry. I'm just trying to find a new writing utensil.
What did you do to prepare for today's deposition?
A. I reviewed the -- the deposition notice, I provided -- I met with my attorneys; I provided computer files, e-mails, and primary and secondary files from our reports.
Q. When did you meet with your attorneys?
A. Two or three weeks ago. I don't remember the exact date. And I also saw them briefly yesterday.
Q. Okay. And how long did you meet with

And then using my highlighter, would you highlight the ones that were -- that are multiple-source, MS?
A. (Complies.)
Q. Now, as you review that schedule, does anything pop out at you in the Percent Saved column for the highlighted columns, multiple-source drugs?
MR. NEAL: Objection as to form.
THE WITNESS: That there is large potential savings for almost all of the -- as far as percent saved, for the multiple-source drugs.
BY MR. TORBORG:
Q. And does that mean there was a larger difference between acquisition cost, as shown in the market and shown in the pricing catalogs, and the AWPs?
MR. NEAL: Objection as to form.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. Okay. Do you recall discussions at OIG relating to the fact that there were such large differences between the catalog prices for



multiple-source drugs and the AWPs for those drugs?
A. I don't recall talking about multiple-source drugs specifically.
Q. How about generics?
A. Or -- or generics specifically. I mean, obviously we did some specific studies on a few of these projects because of the large spreads we found in here.
Q. But fair to say that your -- as reflected in this chart, which provides the detail of your report, right, shows very large savings potential for multiple-source drugs --
MR. NEAL: Objection to --
BY MR. TORBORG:
Q. -- right?
MR. NEAL: -- the form.
THE WITNESS: Again, large savings potential as a -- as a percentage, not necessarily as a total dollar figure.
BY MR. TORBORG:
Q. Do you think it's appropriate to evaluate the differences between prices as a



percentage?
MR. NEAL: Objection as to form.
THE WITNESS: I think it's certainly one way to evaluate it.
BY MR. TORBORG:
Q. You -- do you recall any discussions at any time at OIG with the fact that there was such large spreads for generic multi-source drugs?
A. Not generic as a whole. Again, for a couple particular products, we certainly discussed it.
Q. And which products were those?
A. That would be Albuterol and Leucovorin Calcium, I remember specifically.
Q. What do you recall about Leucovorin Calcium?
A. That in later -- a couple later reports that I worked on, it was a generic, I believe, cancer drug that seemed to have AWPs that were vastly out of line with actual acquisition costs.
Q. Did you have any discussions with individuals at CMS about the large percentage



differences in the -- in the prices for generic drugs between actual acquisition cost, as shown in catalogs, versus published AWPs?
MR. NEAL: I'm going to object to the question.
I'll instruct you not to answer to the extent that those -- your answer would reveal communications that took place in the context of entrance or exit conferences with CMS personnel.
THE WITNESS: Not outside of entrance or exit conferences.
BY MR. TORBORG:
Q. Do you recall having the discussions at all?
MR. NEAL: I'm going to instruct the witness not to answer that question.
MR. TORBORG: Can I ask him whether, without divulging specific communications, if he recall the discussions happening at all?
MR. NEAL: The problem is, the discussions you're talking about involve a specific substance area.

Page 182

MR. TORBORG: That I think is important to the case; that's why I'm asking about it.
MR. NEAL: That may be, but, you know, that -- that doesn't play into our privilege -- privilege assertion, so...
MR. TORBORG: So what you're saying, in essence, is regardless of how important it may be to my defense, you're still going to assert the privilege, no matter what?
MR. NEAL: You can characterize it however you want to. I mean, the fact is, this is an important governmental privilege, and we're going to assert the privilege in this case. We have motions pending on -- you know, on this matter as we speak, and the Court will presumably resolve it for us.
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Q. If we go to Page 10 of your report, Recommendations, what was the purpose for the Recommendations section of the report?

Page 183

A. To make recommendations to CMS about how they could impact or -- or implement some of the changes that would be called for by the findings of our report.
Q. Did you attend the exit conference for this report?
A. I don't believe so.
Q. Do you recall any discussions with CMS about this report?
A. No.
Q. If you look at page -- I'm sorry -- the section under Discounted Wholesale Price, that recommendation, the fifth sentence down, it starts with, In addition. Are you with me?
A. Uh-huh.
Q. It says: In addition, the secretary should be granted the authority to conduct sample surveys of actual wholesale prices to determine the amount of difference between actual average wholesale prices and published AWPs. The percentage difference found in the sample could then be applied to all AWPs used by the program to

Page 184

determine drug reimbursement.
Do you have an understanding of what that recommendation is -- is all about?
A. Yes.
Q. Do you recall discussing -- discussing that recommendation with anyone at CMS at any time?
MR. NEAL: Objection.
You can answer that to the extent that you don't reveal the substance of communications that took place at exit or entrance conferences.
THE WITNESS: No.
BY MR. TORBORG:
Q. The second recommendation is Acquisition Cost. It states: Medicare could base the payment of drugs on either actual or estimated acquisition costs. Although Medicare currently has the authority to use EAC, carriers have yet to successfully implement the option.
Do you recall any discussions about the inability to use the estimated acquisition cost approach in reimbursing Medicare Part B drugs?
A. No.

Page 185

Q. By the time you came in, in 1997, estimated acquisition cost was sort of a methodology of the past; is that fair to say?
MR. NEAL: I'll object to the form.
You can answer.
THE WITNESS: In Medicare, yes.
BY MR. TORBORG:
Q. How about for Medicaid?
A. In Medicaid, as far as I know, estimated acquisition cost is still on the books, and it's up to states to determine the definition -- or not the definition, but it's up to states to determine what estimated acquisition cost is.
Q. Okay. And do you recall any discussions at OIG about whether or not states were implementing that requirement in accordance with the law?
MR. NEAL: Objection as to form.
THE WITNESS: I don't think the law gave them specific instruction about how to implement the requirement.
BY MR. TORBORG:

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

| | | |
|---|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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|---|---|---|
| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC.,<br>et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 262

what's referred to in this report as high-priced generic drugs?
A. No.
Q. What is your understanding of what HCFA's responsibility is with respect to determining how much the Medicaid program reimburses for drugs?
MR. NEAL: Object to the form.
You can answer the question.
THE WITNESS: It's my understanding that they set broad guidelines that states are supposed to abide by, and as long as states are within those broad guidelines, short of any other law or regulation saying otherwise, that -- you know, that the -- they just wanted to ensure that states generally meet the -- meet the guidelines.
BY MR. TORBORG:
Q. What broad guidelines are in existence with respect to Medicaid reimbursement of drugs?
MR. NEAL: Objection as to form.
THE WITNESS: That states should pay either the lower of the estimated acquisition cost

Page 263

or the usual and customary charge for the drug.
BY MR. TORBORG:
Q. Do you have an understanding of what CMS's statutory or regulatory obligation is to assure that states are reimbursing drugs at a true estimated acquisition cost?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: I -- I don't know what CMS's specific authority is to ensure that.
BY MR. TORBORG:
Q. Do you recall any discussions about whether or not CMS was performing its obligation in overseeing the Medicaid program for reimbursement of drugs?
A. In specific Federal Upper Limit studies, I'm sure we looked at the way CMS was sort of ensuring that drugs were added to the Federal Upper Limit List for Medicaid in a timely manner and also ensuring that those prices were appropriate. But as far as, you know, all drugs as a whole, no.
BY MR. TORBORG:

Page 264

Q. And skipping ahead a little bit to tomorrow, what you found with respect to -- to Federal Upper Limits is that CMS was not timely adding drugs to the Federal Upper Limit List, correct?
A. Correct.
Q. And it was your understanding that it was CMS or HCFA's statutory obligation to add qualified drugs -- or drugs that were supposed to be on the Federal Upper Limit List to the Federal Upper Limit List, correct?
MR. NEAL: Objection as to form.
THE WITNESS: Yes, even though the law never said anything about when it had to be done.
BY MR. TORBORG:
Q. Did you have discussions with anyone at CMS about why it was that CMS was not adding drugs to the Federal Upper Limit List that should have been added to the FUL List?
MR. NEAL: Objection.
You can answer that question so long as you don't disclose the contents of any

Page 265

conversations that took place during exit or entrance conferences.
THE WITNESS: The conversations were all in entrance and exit conferences.
BY MR. TORBORG:
Q. Well, let me see if I can ask this. Did CMS officials at the entrance and exit conferences explain to you why it was that drugs were not being added timely to the Federal Upper Limit List?
MR. NEAL: I'm going to instruct you not to answer the question.
It gets into the substance of their --
MR. TORBORG: Just a yes --
MR. NEAL: -- topics --
MR. TORBORG: -- or no question.
MR. NEAL: Answering that question yes or no would reveal the contents of the communications, so...
MR. TORBORG: It wouldn't reveal -- it's just a -- the broad general topic, whether it was discussed.
MR. NEAL: It's on the borderline, but

Page 266

I'm going instruct him not to answer at this time.
BY MR. TORBORG:
Q. Other than a lack of resources, did HCFA provide any other explanations as to why drugs were not being added to the Federal Upper Limit List?
MR. NEAL: Objection.
You can answer that to the extent that you don't reveal the substance of any communications that took place during entrance or exit conferences with CMS.
THE WITNESS: Outside of those conferences, anything -- any explanations that they came up with would have been in their comments to the reports.
BY MR. TORBORG:
Q. Let me see if I can ask that again. Other than a lack of resources at CMS, did HCFA provide any other explanations as to why drugs were not being added to the Federal Upper Limit List?
MR. NEAL: I'll object to the question.
And then you can answer that to the extent that you don't reveal the substance of

Page 267

communications that took place at entrance or exit conferences with CMS.
THE WITNESS: Again, without going back to their official comments to the report, I mean, that's the extent outside of entrance and exit conferences.
BY MR. TORBORG:
Q. At the entrance and exit conferences, did CMS provide any explanations, besides resource-based reasons, why drugs were not being added to the FUL List?
MR. NEAL: I'm going to instruct you not to answer the question.
MR. TORBORG: Just a yes or no, he can't answer that?
MR. NEAL: I'm going to instruct not to answer, yeah, it's -- my objection stands.
MR. TORBORG: So there may be reasons why CMS did not add specific drugs to the FUL List that I'm not going to get to figure out?
MR. NEAL: I mean, your question presupposes certain substantive communications from

Page 268

CMS and --
MR. TORBORG: That's why --
MR. NEAL: -- he's not --
MR. TORBORG: -- I'm asking --
MR. NEAL: -- going to disclose --
MR. TORBORG: -- yes or no.
MR. NEAL: He's not going to disclose those communications.
MR. TORBORG: Well --
MR. NEAL: The objection stands. I'm not --
MR. TORBORG: -- I'm not --
MR. NEAL: -- going to debate --
MR. TORBORG: -- trying to pre --
MR. NEAL: -- with you right now, but, I mean, I -- the objection stands. You're asking about the substance of communications that took place and entrance and exit conferences, and, you know, we've asserted a -- a fairly broad objection over the substance of those communications. I don't think he can answer that even yes or no without disclosing the substance of the

Page 269

communication.
MR. TORBORG: I guess that answers the question in itself, but --
MR. NEAL: I don't know --
MR. WINGET-HERNANDEZ: Objection to form.
MR. NEAL: -- what you're talking about, but...
MR. HAVILAND: John, you're under oath now.
MR. TORBORG: Yeah.
BY MR. TORBORG:
Q. The last paragraph of HCFA's response to this report states: Furthermore, HCFA is undertaking a more comprehensive review of drug prices and how they affect the Medicaid program and will issue future guidance to the states on this as appropriate.
Do you recall HCFA taking a more comprehensive review of drug prices?
A. No.
Q. Do you have any idea what they're referring to there?

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

VOLUME II

| | | |
|---|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

| | | |
|---|---|---|
| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC.,<br>et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 365

inadequate Medicare payments for services related to furnishing the drug, such as the administration of chemotherapy for cancer. We need to pay appropriately for the drugs and the services related to furnishing these drugs.
Do you recall any discussions about that with CMS?
MR. NEAL: You can answer that question to the extent that your answer doesn't implicate any privileged communication.
MR. WINGET-HERNANDEZ: Objection to form.
THE WITNESS: I don't recall any specific discussions outside of entrance or exit conferences.
BY MR. TORBORG:
Q. Did you ever use the term "drug profits" during your time at OIG?
MR. NEAL: Object to the form.
You can answer.
THE WITNESS: I -- I don't recall using that specific term.
BY MR. TORBORG:

Page 366

Q. Did you ever use -- do you ever recall using the term "cross-subsidize"?
A. I don't think I would have used that specific term either.
Q. Do you recall anyone else using that term?
A. Aside from -- that specific term, aside from these comments, no.
Q. Do you recall any discussions within OIG or CMS about the concept of the payment for the drug making up for underpayment for physician services?
MR. NEAL: You can answer that consistent with my previous instruction on privileged communication.
MR. WINGET-HERNANDEZ: Objection to form.
THE WITNESS: I recall those discussions. However, again, I'm not sure that it was -- it was more along the lines of this is what physicians say. There was no real discussion of the validity of -- of the physicians' claims.
BY MR. TORBORG:

Page 367

Q. Because OIG had never studied that particular issue, right?
MR. NEAL: Objection as to form.
THE WITNESS: As far as I know, at least OEI had not studied that issue.
BY MR. TORBORG:
Q. Do you recall CMS ever asking OIG to study that issue?
MR. WINGET-HERNANDEZ: Objection to form.
THE WITNESS: I recall being asked to look at the dispensing-fee issue. I don't necessarily recall being asked to look into physician service costs.
BY MR. TORBORG:
Q. What do you -- what do you recall about being asked to look at the dispensing-fee issue?
A. In converse -- in conversations with CMS, them asking how much it really cost physicians -- I'm sorry -- how much it really cost the pharmacies to dispense the drugs and what services they're -- they're providing for those dispensing fees.

Page 368

Q. And just to back up a step, what is a dispensing fee?
A. A dispensing fee is a fee paid with each prescription filled by a pharmacy.
Q. Is the dispensing fee supposed to include a level of profit?
MR. NEAL: Objection as to form.
THE WITNESS: I am not sure about the -- about what it's supposed to include.
BY MR. TORBORG:
Q. With whom did you have these conversations?
MR. NEAL: Let me just instruct you to answer that question consistent with my previous instruction. You can discuss this so long as you don't implicate essentially privileged communications at entrance and exit conferences.
THE WITNESS: I don't recall exactly who was at the meeting. It would have been someone that I mentioned earlier as folks that I had met with, but I can't remember specifically who was there.

Page 393

worked with in the last year on Federal Upper Limit topics.
Q. Do you remember an individual named William Scanlon (ph)?
A. I've -- I've heard that name, but I don't know exactly who he was. I know I never --
Q. That's not --
A. -- spoke with him.
Q. That's not one of the people that you --
A. No.
Q. -- talked with? Okay. In the bottom of the first column, last paragraph, it states: There's no doubt there are problems with AWP-based payments, acknowledged Susan Winckler, group director of policy and advocacy for the American Pharmaceutical Association. She agreed that AWP is neither an average price nor a wholesale price. But focusing on AWP distracts attention from the real problem - payment for professional services.
Quote, if you want to base drug payments on more accurate figures, fine, Winckler said, but that must be coupled with an acknowledgment of all

Page 394

the costs involved in getting the product out the door. We can unbundle the costs of professional, administrative, and distributive services, but we cannot ignore -- but we can't ignore them. No other business is expected to sell products at cost or lower.
Do you agree or disagree with the statements made by Ms. Winckler as quoted in this article?
MR. NEAL: Objection as to form.
MR. WINGET-HERNANDEZ: Compound.
THE WITNESS: In relation to pharmacies, I don't disagree that businesses aren't expected to sell products at cost or lower. And I think that in order to determine -- in -- in order to ensure that providers are reimbursed fairly, that both segments need to be considered. That's why it -- you know, that's why those recommendations were typically in our reports.
BY MR. TORBORG:
Q. If we go to the -- to the third column, there is a quote from John Rector, vice president of the government affairs and general counsel for

Page 395

the National Community Pharmacists Association. And the article states: Focusing acquisition -- focusing on acquisition cost sounds good in congressional testimony, but it's a recipe for financial disaster.
Do you see that?
A. Yes.
Q. Do you recall any discussions with OIG or HCFA of what would happen if CMS changed the way it reimbursed for drugs?
MR. WINGET-HERNANDEZ: Objection to form.
MR. NEAL: I'll object to the form as well.
You can answer that question to the extent that your answer would not divulge any privileged communication.
THE WITNESS: In various conversations, I know that especially in the pharmacy area, not necessarily in the physician area, that there -- and that's why we had conversations about dispensing fees -- that CMS wanted to ensure that -- that beneficiary access wasn't inhibited based

Page 396

on any -- based on any cost reductions.
BY MR. TORBORG:
Q. Do you recall who made those -- with whom you had those conversations?
A. No.
Q. Do you have a recollection of when those conversations occurred?
A. They have occurred recently about the Federal Upper -- the Federal Upper Limit work that we've done. They -- I don't recall earlier conversations. They were most likely done in entrance or exit conferences, some of them, and others during work planning meetings.
Q. A fairly frequent topic of conversation?
A. No. I mean, maybe once a year at most.
Q. With respect to the recent work you're doing on Federal Upper Limits, you indicated that you had discussions with CMS about what I'll call the access issue; is that fair to say?
MR. NEAL: I'll --
MR. PAUL: Objection to --
MR. NEAL: I'll object to the form.

You can answer.
THE WITNESS: Yes.
BY MR. TORBORG:
Q. And with whom did you have conversations; do you recall?
A. Larry Reid and Deirdre Duzor.
Q. And do you -- what can you recall about those conversations?
MR. NEAL: You can answer that question consistent with my previous instruction on privileged communication.
THE WITNESS: It was simply based on initial results from a draft report that we're working on and how the new Federal Upper Limit amounts related to actual acquisition costs for pharmacies.
BY MR. TORBORG:
Q. And what stage is that report at right now?
A. We're awaiting comments from CMS, so it's a draft report.
Q. And so you've received some oral



comments from CMS?
A. Yes.
Q. But not formal?
A. Correct.
Q. How long ago -- how long ago did you receive the oral comments?
A. Two or three months ago.
Q. Is there any record of those oral comments?
A. Yes.
Q. Did you take notes?
A. Yes.
Q. Where -- where are those notes today?
A. They would be part of the exit conference notes.
Q. Anything else you -- you can recall about the specifics of those conversations?
MR. NEAL: You can answer that question consistent with my previous instructions.
THE WITNESS: No.
BY MR. TORBORG:
Q. Is CMS concerned that basing the Federal



Upper Limits on AMP data may cause an access issue?
MR. NEAL: Objection as to form.
You can answer that question consistent with my instruction on privileged communications.
THE WITNESS: Since I haven't seen their official comments, I can't say what the official position of CMS is.
Outside of exit conference, there have been a couple conversations involving the data that we have that does -- that -- where they did indicate that there may be some small issues that they're concerned with. You can also look at their comments to the GAO report which -- and which looked at the same issue that we're looking at in this and -- and get a better idea of where they -- where they stand.
BY MR. TORBORG:
Q. Do you recall in other conversations you've had with CMS relating to the Federal Upper Limit issue and -- let me back up.
You've done other reports on Federal Upper Limits --



A. Yes.
Q. -- correct? Starting, I think, in about 2004?
A. It may have been earlier. I'm not sure.
Q. Have any of the conversations you've had with CMS relating to those reports discussed the access issue?
MR. NEAL: I'll instruct you not to answer that question to the extent that it will require you to divulge privileged communications with CMS.
THE WITNESS: Outside of entrance and exit conferences, there were a few discussions about how Federal Upper Limits were calculated and concerns that sometimes that the lowest price available -- or the lowest price listed in compendia wasn't accurate and not available to -- to all pharmacies, and, therefore, setting the Federal Upper Limit amount based on that price could lead to access issues.
BY MR. TORBORG:
Q. Do you recall with whom those

Page 489

state Medicaid agencies would have access to that information. In September 1995, CMS addressed this issue in response to comments received on a proposed rule regarding Medicaid payment for outpatient drugs. The CMS asserted that they would not disclose AMP to states, but maintained that the statute contemplates a disclosure of manufacturer pricing data to the states, and that they believe Congress intended that states have access to sufficient pricing information to implement the Medicaid drug rebate program.

Do you recall any conversations at any time, Mr. Tawes, regarding the ability of CMS to share AMP data with states?

A. Yes.

Q. Okay. Tell me what you recall about those conversations.

MR. NEAL: I'll just instruct the witness:

You can answer that question to the extent that your answer would not implicate privileged communications that you may have had.

Page 490

THE WITNESS: Simply a difference of opinion between CMS and some of the folks in Region 5 OIG, and I would assume O -- the OIG in general, as to whether CMS could provide AMP data to states.

BY MR. TORBORG:

Q. Did Region 3 of OIG have a position on that issue?

MR. NEAL: Objection as to form.

THE WITNESS: No.

BY MR. TORBORG:

Q. Had you ever evaluated that issue yourself?

A. No.

Q. What do you recall about conversations regarding this issue; who were they with, when they were --

A. It would have --

Q. -- what was said?

A. It would have been with -- with various staff in Region 5 -- Madeline Francescatti, Ann Maxwell, Erin Lemire, just about whether they believed states -- or CMS could provide this data to states or not.

Page 491

Q. Do you recall what they said?

A. That they believed that -- that CMS could provide this information to states.

Q. Did they make any comments about why CMS was narrowly interpreting the confidentiality clause?

MR. NEAL: Objection as to form.

THE WITNESS: Not that I recall.

BY MR. TORBORG:

Q. Have you ever formed any opinion on this yourself?

MR. NEAL: I'll object to the form.

You can answer.

THE WITNESS: No.

BY MR. TORBORG:

Q. Do you know if Mr. Vito has formed any opinion on this?

MR. NEAL: The same objection.

You can answer.

THE WITNESS: No.

BY MR. TORBORG:

Page 492

Q. If I could ask you to go to the 2004 report that you did relating -- entitled, Omission of Drugs From the Federal Upper Limit List in 2001, and then if you would -- do you have the exhibit number there?

A. Exhibit Abbott 108.

Q. Thank you. And this is a report that you were the team leader for?

A. Yes.

Q. And did you draft this report?

A. Yes.

Q. Did you share this report with state Medicaid programs?

A. I don't believe so.

Q. And in summary, can you explain to the jury what you found in this report?

MR. NEAL: Objection as to form.

THE WITNESS: We found that numerous drugs that met the established criteria for being included on the Federal Upper Limit List -- on the Federal Upper Limit List were not being included on the list in 2001.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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|---|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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|---|---|---|
| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC.,<br>et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 330

was following the fact that they had to pay at AWP.
BY MR. COOK:
Q. And to the extent that HCFA promulgated a regulation, HCFA determined that it believed, at least, that that was the appropriate amount, correct?
MR. NEAL: Objection as to form.
THE WITNESS: I don't know if they felt it was appropriate.
BY MR. COOK:
Q. Did you ever discuss with anybody at HCFA what they thought was an appropriate amount of reimbursement?
MR. NEAL: I'm going to object to the question.
In fact, I'm going to instruct you not to answer to the extent that that would reveal any communications that took place at exit or entrance conferences. You've stated that you didn't -- you don't have any recollection of those conferences.
If you can answer the question without referring to any communications that took place

Page 331

there, you can answer the question.
THE WITNESS: Would you repeat the question again, please?
BY MR. COOK:
Q. Sure.
MR. NEAL: That was a lengthy objection. I apologize. There are privilege concerns.
BY MR. COOK:
Q. Did you ever discuss with anybody at HCFA what HCFA believed would be an appropriate amount of reimbursement for drugs under Medicare Part B?
A. I don't remember if we discussed that at the entrance and exit conferences.
Q. At any time, with any HCFA official, did you discuss what an appropriate amount of Medicare reimbursement would be?
A. I don't remember discussing what the exact amount of appropriate reimbursement would be.
Q. Leaving aside an exact precise amount, do you remember discussing with any HCFA officials how one would go about determining an appropriate

Page 332

level of reimbursement for Medicare Part B paid drugs?
MR. NEAL: Objection.
You can answer that to the extent that you do not reveal communications that took place at entrance or exit conferences.
THE WITNESS: I believe based on the options we provided them, those were some of the -- the discussion was based on the -- our recommendations.
BY MR. COOK:
Q. Do you recall, did HCFA implement any of your recommendations?
A. I -- can I go back and read them?
Q. Sure.
A. May I go back and read them?
Q. Absolutely. It's at Page 7 of Exhibit Abbott 060.
A. I believe, and I don't remember if it was regulatory or legislated, that there was a change made to AWP in later years to provide that Medicare pay a discounted rate.

Page 333

Q. And that would be 95 percent of AWP; is that correct?
A. That's the figure I remember.
Q. And that would have been the Balanced Budget Amendment -- Balanced Budget Act of 1997; does that sound right?
A. It sounds right.
Q. Okay.
A. I don't believe that they'd ever instituted a manufacturer rebate. I do believe that there are items being competitively bid now. I recall discussions about inherent -- inherent reasonableness. I do not know if CMS ever did it. And I do not believe that they have -- are paying based on an estimated -- based on an estimated acquisition cost, using that term.
Q. And so you made the recommendation that discounted wholesale price would get to, perhaps, an appropriate reimbursement amount for Albuterol Sulfate, correct?
MR. NEAL: Objection as to form.
THE WITNESS: I think that the

Page 366

Q. Did you have a range of amounts that would have been appropriate in mind?
MR. NEAL: The same objection.
THE WITNESS: I don't -- I don't remember exactly what I recalled at the time I was writing this, but I don't think I had a range of amounts that I thought would be appropriate.
BY MR. COOK:
Q. And sticking with the summary findings, you found that the Department of Veterans Affairs -- well, let me switch that over and strike that.
You found that Medicare pays between 56 percent and 550 percent more than the Department of Veterans Affairs for Albuterol Sulfate in 1998; is that correct?
A. That's the way I read that statement.
Q. And that was the finding in the report that you drafted, correct?
A. Yes.
Q. And as the project leader, you would have drafted the report?
A. Most likely, yes.

Page 367

Q. And the second point under this was that Medicare allowed 20 percent more than the average Medicaid payment for Albuterol Sulfate in 1997; is that correct?
A. Yes.
Q. You further found that Medicare allowed up to 333 percent more than acquisition costs available for Albuterol Sulfate in 1998, correct?
A. Yes.
Q. And finally, you found that the customers of mail order pharmacies would pay up to 30 percent less than Medicare for Albuterol Sulfate in 1998, correct?
A. Yes.
Q. Do you remember what it was that prompted you to issue an additional report in August 1998, following your June 1996 report on Albuterol Sulfate?
A. I don't remember.
Q. To your knowledge, had HCFA taken any actions to respond to the recommendations in your June 1996 report at the time you issued this August

Page 368

1998 report?
MR. NEAL: Objection as to form.
You can answer.
THE WITNESS: I -- I don't remember. I'd have to read the comments, the CMS comments of the report.
BY MR. COOK:
Q. And where would I find those?
A. If the agency commented, it would be in the back -- it's in the back of the report.
Q. And so that would be this June 11, 1998 memo to June Gibbs Brown from Nancy-Ann Min DeParle; is that correct?
A. Yes.
Q. Looking at that report, it indicates: We reviewed the above-referenced report.
Any reason to believe that the Health Care Finance Administration had not reviewed the report?
A. I have no reason to believe that, since the statement says that they reviewed it.
Q. It indicates, in the second paragraph there, that: HCFA concurs with the intent of the

Page 369

OIG report recommendation.
And then goes on to make specific responses.
Do you recall HCFA concurring with the intent of your recommendations in June of 1998?
A. I do not recall it. I'm reading it here now.
Q. But you would have had communications with HCFA officials, correct?
A. This would have been the official communication on their concurrence or nonconcurrence with the findings and recommendations of the report.
Q. But in addition to this, you would have had an entrance -- an entrance meeting, right?
A. Normally we would. I can't tell you if we absolutely had it for here. We would have normally had an entrance and an exit conference for this report.
Q. Any reason to believe that any of the sentiments expressed in the entrance and exit conferences for this report varied from the official responses given by Ms. Min DeParle in this

Page 370

memo?
MR. NEAL: I'm going to object to the question and instruct you not to answer.
BY MR. COOK:
Q. Ms. Ragone --
MR. MERKL: You're not going to let her answer that yes or no?
MR. NEAL: Answering it yes or no would possibly implicate the substance of communications that she had in an exit conference concerning this report.
BY MR. COOK:
Q. Generally speaking, Ms. Ragone, did you ever find it to be the case that your oral communications with officials at HCFA conflicted at all with the written responses that they would submit to the Office of Inspector General?
MR. NEAL: You can answer that generally.
THE WITNESS: Generally, for our -- in our -- all of our inspections, not just prescription drugs, there have been times when there haven't been what we believed to be

Page 371

objections raised during these conversations, and then when we get the formal comments, there will be technical comments or objections raised that we never heard at the exit conference.
BY MR. COOK:
Q. And so if -- back up one. Have you ever had the experience where an objection was raised at the exit conference that was not reflected in the written --
A. Yes --
Q. -- comments?
A. -- I believe I've had an experience where somebody has raised a personal objection, their feelings, and that doesn't become part of the formal comments back to our agency.
Q. And so if Abbott and the other defendants were seeking to determine what it is that HCFA knew and what it is that HCFA intended to do when it comes to Medicare reimbursement, we would need to find out what was said at the exit conference to get a complete picture of what the agency knew and intended, correct?

Page 372

MR. NEAL: I'm going to object --
MS. POLLACK: Objection.
MR. NEAL: -- to the form of the question.
THE WITNESS: I don't know --
MR. NEAL: You can answer.
THE WITNESS: I don't know if you would get from those what the whole agency intended or knew about it. You would just -- if you heard anything, it would be the people that were in that room, and not everybody in those converse -- in those conferences speaks, so I don't know what you would get from those. I don't remember the conversations.
BY MR. COOK:
Q. But there would -- you admit that there would be more information about what the agency knew and intended from those communications than from simply the written comments submitted, correct?
MR. NEAL: I'm going to object to the form of the question.

Page 373

THE WITNESS: I believe that there are statements made during those conferences that do not appear in the formal written comments.
BY MR. COOK:
Q. Do you know why?
A. I don't know why. I believe that it's because it's an informal conversation. I mean, we often will provide them with details during those conferences that we discuss back and forth. As I said, sometimes there's conversation, sometimes there's not a lot of conversation. It varies based on the report.
Q. The first OIG recommendation listed in this June 11, 1998 memorandum says: HCFA immediately reduced Medicare reimbursement for Albuterol Sulfate by 15 percent, using the new authority outlined in the Balanced Budget Act of 1997.
That's on Page A2.
A. Well, you're looking at their comments. Yes.
Q. Yes, ma'am. I'm looking at that the

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

VOLUME II

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|---|---|---|
| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | : | MDL NO. 1456<br>CIVIL ACTION:<br>01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: | : | |
| U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc. | : | CIVIL ACTION:<br>06-CV-11337-PBS |

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

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|---|---|---|
| STATE OF ALABAMA,<br>Plaintiff,<br>v.<br>ABBOTT LABORATORIES, INC.,<br>et al.,<br>Defendants. | : | CASE NO.<br>CV-05-219<br><br>JUDGE<br>CHARLES PRICE |

Page 477

A. It goes -- right now it goes up on the Internet, yes.
Q. And the purpose of that distribution process is to put these reports in the hands of policymakers, who can use this information in making policy decisions?
MR. DRAYCOTT: Objection.
MR. COOK: What's the objection?
MR. DRAYCOTT: For one, you didn't, first of all, establish that she would know what the purpose for the distribution is when you asked her what the distribution -- what the purpose is.
BY MR. COOK:
Q. If I ever ask you a question, Ms. Ragone, and you don't know the answer, feel free to say I don't know.
Can you tell me whether one of the purposes of distributing these reports was to put it in the hands of policymakers who can use this information in making policy decisions?
A. I believe it is our hope that by putting these findings and recommendations together and

Page 478

putting them in published reports, that the people who this information would be germane to would read it and have access to it.
Q. Now, this was in December 1997. Do you know if anytime after December 1997, HCFA, later CMS, abandoned AWP as the benchmark for reimbursing Medicare Part B drugs?
A. I haven't been in the drug arena as much at the end. I believe that they are using new strategies now, reimbursement methodologies, in Medicare.
Q. When was it that you left the prescription drug -- was that 2004?
A. There were a few times I had been the DRIG, and then a team leader, Dave Tawes, began leading most of the drug work, and he would work more often directly with our manager, Robert Vito, so the actual pricing work, I haven't done in quite some time.
Q. As of 2004, was Medicare still using AWP to base its Medicare Part B drug reimbursement?
A. I don't remember what the time period

Page 479

was when it changed to --
Q. Can you give me a rough? After 2000?
A. Yes.
Q. After 2002? After 2001?
A. I think after 2002. I'm not quite sure when the legislation was enacted.
Q. So whenever the legislation was enacted, perhaps for as many as five years after receiving the conclusions of this report, Medicare Part B continued to pay, for the 22 drugs reviewed in this report, based upon AWP, correct?
MR. DRAYCOTT: Objection.
THE WITNESS: Based upon, I guess, starting in 1998, they paid AWP minus 5 percent.
BY MR. COOK:
Q. But still based upon the AWP?
A. Correct.
Q. Did you ever have an argument with anybody at HCFA about the wisdom of doing that?
MR. DRAYCOTT: Objection.
THE WITNESS: I'm not -- I don't know if I would call it an argument. We've certainly had

Page 480

discussions during exit conferences about the fact that a different pricing methodology might be appropriate.
BY MR. COOK:
Q. What do they say about that?
MR. DRAYCOTT: Objection.
Instruct you not to answer.
BY MR. COOK:
Q. I know you're going to be instructed not to answer, but I do have to put the questions on the record, Ms. Ragone.
So let me get this straight. You sit down in a room, at a conference table like this with folks from HCFA; you tell them that AWP exceeds acquisition costs, as defined in the report, by up to ten times, right?
A. Yes.
Q. You tell them that the OIG recommends that they stop paying that high an amount for prescription drugs, right?
MR. DRAYCOTT: Objection to the extent that you're asking for the contents of her

Page 481

communications to HCFA during the exit conference.
MR. COOK: If you'd just instruct her not to answer. Are you instructing her not to answer?
MR. DRAYCOTT: I am.
BY MR. COOK:
Q. So you make whatever communications you do to HCFA in these exit conferences --
MR. DRAYCOTT: Objection.
BY MR. COOK:
Q. -- after giving them a copy of this report, right?
MR. DRAYCOTT: Objection.
And you're instructed not to answer.
BY MR. COOK:
Q. And you make your recommendations, correct?
MR. DRAYCOTT: You can answer that question.
THE WITNESS: During the exit conferences, we will tell them the findings and recommendations.
BY MR. COOK:

Page 482

Q. And you encourage them, that is, officials at HCFA, to reimburse prescription drugs based upon something other than the published average wholesale price?
MR. DRAYCOTT: Objection.
You're instructed not to answer.
BY MR. COOK:
Q. And, in fact, you do so heatedly, correct?
MR. DRAYCOTT: Objection.
And you're instructed not to answer.
BY MR. COOK:
Q. And they respond?
MR. DRAYCOTT: You can answer whether or not they responded.
THE WITNESS: If they have comments, they will respond when we provide the findings and recommendations.
BY MR. COOK:
Q. Did they explain why HCFA continued to pay based upon AWP, notwithstanding the fact that HCFA knew average wholesale price could exceed

Page 483

acquisition cost by as much as ten times?
MR. DRAYCOTT: You can answer as to whether or not they responded without revealing the response, if you remember.
THE WITNESS: I believe that they stated why they were using the reimbursement strategy they were using at that time.
BY MR. COOK:
Q. And what was their explanation?
MR. DRAYCOTT: Objection.
And you're instructed not to answer.
BY MR. COOK:
Q. Why do you believe HCFA continued to use average wholesale price to pay for Medicare Part B drugs after you issued this report in December 1997?
MR. DRAYCOTT: Objection.
And you're instructed not to answer to the extent your belief is based on communications from HCFA during an exit conference.
BY MR. COOK:
Q. I'll let you work out that metaphysical

Page 484

problem.
A. I -- I believe --
MR. DRAYCOTT: Well --
THE WITNESS: -- that the --
MR. DRAYCOTT: Let me ask you: Can you answer that question without revealing the content of communication from HCFA during the conference?
THE WITNESS: I believe I can. I believe I can.
MR. DRAYCOTT: Okay.
THE WITNESS: I believe that the level of people that we were talking to believed that the regulations or legislations were set for payment at a certain place and that that's what Medicare was bound to reimburse at.
BY MR. COOK:
Q. Who at HCFA is responsible for setting Medicare Part B drug payment policy?
A. Policy?
Q. What the amount is that they would pay.
A. I believe that would be regulated or legislated.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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| IN RE: PHARMACEUTICAL | ) | MDL NO. 1456 |
| INDUSTRY AVERAGE WHOLESALE | ) | CIVIL ACTION |
| PRICE LITIGATION | ) | 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO | ) | |
| U.S. ex rel. Ven-a-Care of | ) | Judge Patti B. Saris |
| the Florida Keys, Inc. | ) | |
| v. | ) | Chief Magistrate |
| Abbott Laboratories, Inc., | ) | Judge Marianne B. |
| No. 06-CV-11337-PBS | ) | Bowler |

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Videotaped deposition of AMY BASSANO

Baltimore, Maryland

Wednesday, November 7, 2007

9:00 a.m.

Page 82

reviewing the legislation, the regulations, OIG reports and what you might pick up from discussions with other people?
A. Yes.
Q. Anything else?
A. No.
Q. Can you testify about the conduct of any drug manufacturers from 1991 through 2001?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No.
Q. Do you have any personal knowledge regarding Abbott or any of the other drug manufacturers did or did not report to drug pricing compendia from 1991 to 2001?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No.
Q. Can you testify from your personal knowledge as to what CMS understood about drug pricing in the industry from 1991 through 2001?
MR. DRAYCOTT: Objection. You can answer

Page 83

if you can.
A. No.
Q. Can you testify from your personal knowledge regarding the comparison of AWP to actual acquisition cost from 1991 through 2001?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No.
Q. Can you testify from your personal knowledge about any of the allegations that Abbott committed fraud?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No.
Q. Do you have any personal knowledge regarding the allegations that Abbott caused false claims to be submitted?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No.
Q. Okay. Let's talk about what you could testify about. Regarding Medicare Part B

Page 84

reimbursement for drugs what testimony could you offer -- well, actually, let me step back and let me strike that.
Do you have an understanding of when Medicare first began paying for Part B drugs?
A. Yes.
Q. When was that?
A. I believe at the beginning of the inception of the Medicare program.
Q. Which would have been?
A. 1965.
Q. Do you know when they first began basing payments for Part B drugs on AWP?
A. I believe it was sometime in the 1980s or '90s.
Q. Do you know why from your personal knowledge AWP was selected as opposed to some other methodology for paying for Part B drugs?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No, I don't.
Q. Do you know if any other options aside

Page 85

from AWP were considered?
MR. DRAYCOTT: Objection. You can answer if you can.
A. When?
Q. From 1991 through 2001.
A. Sorry. Can you ask me the question again?
Q. Okay. Do you know if any other options aside from basing payment for Part B drugs on AWP were considered from the period 1991 through 2001?
THE WITNESS: Should I answer?
MR. DRAYCOTT: The answer is just -- you asked the question is she aware.
Q. Are you aware, were there any other options considered?
MR. DRAYCOTT: You can answer that yes or no.
A. 1991 to 2001? I believe there may have been.
Q. And is this based upon your personal knowledge?
A. No.

Q. Based upon your review of historical documents?
A. No.
Q. What is it based on?
A. Conversations with other people.
Q. Conversations with people who worked with CMS at the time?
A. Yes.
Q. And they said other options aside from AWP were considered?
A. Yes.
Q. What were those options?
MR. DRAYCOTT: Objection to the -- I mean, what is the context in which you're asking this? I mean, if you're talking about -- if you're going through internal deliberations within CMS policy making areas, such as the Office of Legislation where Ms. Bassano worked then I'd instruct her not to reveal the content of those deliberations within OL to the extent they were before developing a policy regarding reimbursement methodology.



You've asked a very broad question. So I'm going to object to the question based on its breadth. I can try to instruct the witness to answer if she can with respect to non-privileged information or it may help to clarify the question.
Q. Could you answer with respect to non-privileged information what other options aside from AWP were considered?
A. No. Because I don't recall what actually ever was made public versus what was discussed internally and just had been considered.
Q. In what perform was it considered?
A. What does that mean?
Q. Was it considered through policy papers? Was it considered just in discussions in meetings?
MR. DRAYCOTT: If you can answer the question or if you have a recollection about the particular format --
A. I don't know. No one ever specifically -- I don't know what formats it was considered in.
Q. And was that something that you



personally worked on for the Office of Legislation or is it something you were told in discussions?
A. Something I was told.
Q. Who told you this?
A. I don't recall specifically. I heard it from various sources over time, various individuals over time.
Q. Do you remember any of them by name?
MR. DRAYCOTT: You can name the individuals.
A. As I said earlier, Don Thompson and Parashar Patel were my main contacts at CMS on this particular issue.
Q. Do you know what their positions were between 1991 and 2001? Let's start with Mr. Thompson.
A. Not specifically.
Q. Okay. Generally what section they worked in?
A. He -- I know he began his time at CMS in the Office of the Actuary. And then he moved to the Hospital and Ambulatory Policy Group, at it wasn't



called that at that time. It's been through a variety of reorganizations. But generally Medicare payment policy area.
Q. What about Mr. Patel? What positions did he hold to the best of your knowledge from '91 through 2001?
A. At least for the very tail end of that period he was the deputy group director of the precursor to the Hospital and Ambulatory Policy Group. He -- when I first met him in 1999 he was the special assistant to the person who was the head of, again, the precursor to the Center for Medicare Management.
Q. Now, when AWP was first implemented as a method for payment for Part B drugs what is your understanding of the methodology on which that payment was based?
MR. DRAYCOTT: Objection. You can answer if you can.
A. I'm sorry. I don't understand the question.
Q. You've mentioned that AWP was first used

Page 106

being defrauded by a drug manufacturers?
MR. DRAYCOTT: Objection. You can answer if you can.
A. What were those first couple words? I didn't --
Q. Have you ever encountered a situation in which you believe that the Medicare system was being defrauded by a drug manufacturer?
MR. DRAYCOTT: Objection. You can answer if you can.
A. No.
Q. Do you know whether during the period of 1991 through 2001 CMS relied on AWP to reflect the prices providers actually paid for drugs?
A. Can you -- I'm confused about the second part of your question.
Q. From 1991 through 2001 was CMS to your knowledge relying on AWP to reflect the actual market prices for drugs?
MR. DRAYCOTT: Objection. But you can answer.
A. I don't know.

Page 107

Q. Did you discuss that with anyone who was working at CMS on Part B issues from '91 through 2001?
A. If it reflected actual market prices?
Q. Yes.
MR. DRAYCOTT: You're looking at me -- when you're looking at me is it because of a concern that you're being asked for privileged information or --
THE WITNESS: Well, it's sort of what can I say about conversations I've had or didn't have with people at CMS.
MR. DRAYCOTT: Well, it depends -- certainly what you can't testify about are conversations that would be covered by an attorney-client privilege or work product privilege such as conversations with office of general counsel or the Department of Justice. And you also can't testify as deliberative conversations that were directed at implementing or changing or considering the change to a policy.
If Mr. Gabel's question -- I think -- it

Page 108

is a broad question -- is as to how something was implemented and how a policy was implemented, you can testify to that. So if it's the conversations that he's referring to -- and I understand why the question is difficult --
MR. GABEL: Let me restate the question.
MR. DRAYCOTT: Yeah. I think you need to be more specific in your question.
MR. GABEL: I will.
BY MR. GABEL:
Q. Are you aware of anyone from the period of 1991 through 2001, anyone at CMS who relied on AWP to actually reflect the prices paid for drugs in the marketplace?
MR. DRAYCOTT: Objection. But you can answer it if you can.
A. I don't think anyone personally relied on the AWP or held it out and said this is the actual market price.
Q. And have you reviewed OIG reports from the period of '91 through 2001?
A. Yes.

Page 109

Q. And those reports actually stated that AWP was not an accurate reflection of market prices, right?
MR. DRAYCOTT: Objection. But you can answer.
A. I don't remember the exact words in the IG report, but I think that was the general sentiment expressed in their findings.
Q. In fact AWP exceeded market prices by a considerable amount according to those OIG reports, right?
MR. DRAYCOTT: Objection, but you can answer to the extent you have an opinion.
A. Yes. I believe those were the findings of the reports.
Q. Have you ever heard allegations that the manufacturers were marketing the spread on their drugs?
A. Yes. I've heard that term.
Q. Do you have any personal knowledge regarding those allegations?
A. No.